# About the User's Manual

The User's Manual serves for operating this instrument only. Our company shall not be responsible for any consequences and liabilities caused by using this user's manual for other purposes.

The User's Manual containing special information is under copyright protection. All rights reserved. Copy, duplication or translation of the whole or any part of the User's Manual is prohibited in case of no prior written consent from our company.

Based on the need of product technical improvement or the file updates, we reserve the right to modify the contents contained in this manual; if the changes do not involve safety issues, the contents are subject to amend without notification

Due to technical upgrade or special requirements from users and with the precondition that the performance of the instrument will not be lowered, some components may vary from the description of configuration in the User's Manual.

**The explain for tagging in this manual**

⚠ **Warning :** You should know the information for how to avoid the patients and medical staff may suffer injury.

**Note:** You should know the information for how to avoid possible damage to equipment.

**Explain:**The important information you should known.

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# Foreword

Thank you for choosing the digital electrocardiograph series products produced by the company. In order to ensure the safety of you, the patient and the product, please carefully read this manual before using, which can provide you with a series of safety reminders and application guidance, helping you successfully reach the expected goal during the process of usage. In this user's manual, the descriptions with the symbol ⚠ are matters needing especial attention, which may involve information about the safe usage of the product, so please pay extreme attention to those matters.

In order to provide assistance to users intuitively, the manual quoted some pictures as reference. As the product undergoes improvements continuously, the detailed information on parts of the pictures may be inconsistent with the actual situation, but these differences would not affect the normal operation and interpretation of the users, so can be ignored. At the mean time, the manual also described the expansion optional functions of the product, which can only be realized when you have purchased the product with those optional functions, so please identify it.

Digital electrocardiograph is used to record and display the biopotential signals generated by the activities of the heart. It mainly uses ECG electrode to extract biopotential signals from human body, which are transmitted, filtered and amplified through the lead input network, transferred into numerical information by A/D, sent into the recorder and display after digital processing, and thus the ECG waveforms can be recorded and displayed. In view of the specialization of its applications, the product can only be used by medical personnel with professional qualifications in hospitals, clinics or medical centers, as well as first aid sites. As the complexity of the physiological structure of human body and the diversity of the causes of diseases, the automatic diagnosis results given by the product are for reference only, which shall be complemented by professional doctors' comprehensive diagnosis according to the actual situation of the patient.

According to the classification principles of Medical Electrical Equipment Part I: General Requirements for Safety (IEC 601-1) the digital electrocardiograph is classified into the following category:

- Anti-shock category: category I, equipment with built-in power supply.
- Anti-shock level: CF type applied part
- Degree of protection against harmful inflow liquids: normal equipment (enclosed equipment with no protection against harmful inflow liquids.

- Degree of safety when used with mixed gas of flammable anesthetic gas with air, oxygen or nitrous oxide: the equipment cannot be used with mixed gas of flammable anesthetic gas with air, oxygen or nitrous oxide.
- Duty: continuous running equipment.

Some symbols are used to represent specific information in the manual and the nameplate, sign and mark of the product, which are listed as follows for you to recognize:


**AC Working Mode**

**DC Working Mode**

**Battery Charging**

**Equipotential Point**

**AC Power Supply Cut off**


**AC Power Supply Connected**

**RS232 Interface**

**Signal Output**

**Signal Input**

**Notice! Please refer to the attached document**

**Type CF applied part**

**Type CF defibrillation-proof applied part**

**Note:**

**Refer to the menu of status setting for Information items and interpretations on the display screen**

# Chapter 1. Common Matters Needing Attention

★ **The device is for the exclusive use of licensed physicians or personnel.**

★ **Please read the following precautions thoroughly prior to using this instrument.**

★ **Applicability: It is applicable to perform the routine diagnosis via electrocardiogram for various medical therapy units, particularly in cases such as health examinations, outpatient & emergency departments and wards of hospital.**

⚠ **Warning: The following measures should be taken when installing or storing the instrument:**

- Keep the instrument away from splashing water, and do not use or install it where air pressure, humidity, temperature, ventilation, air containing dust, sulfur, salt, alkaline gas and chemicals might affect it .
- Install the instrument on a stable plane, and prevent it from vibration and mechanical shock when moving it.
- Install it in a room with complete infrastructure.
- There should be no high capacity machine such as high voltage cable , X-ray &ultrasound device as well as diathermy machine around this electrocardiograph.

⚠ **Warning:**

- The power supply should be capable of providing the proper voltage and frequency as required in the instruction manual as well as sufficient capability.
- Do not install the instrument in a chemical storage area or where gas is generated.

⚠ **Warning: Prior to operation:**

- Check that the instrument is in a complete and normal condition.
- Check that the instrument is properly installed.
- Check that all cables are connected correctly and the instrument is grounded correctly.
- It should be given particular attentions when using this instrument with other devices to avoid misdiagnosis or other problems.
- All circuits that contact the patients directly should be examined closely.
- When battery used, please check the voltage and condition of battery first, charge and discharge the battery, and keep the battery fully charged.

⚠ **Warning：In operation**

- The physician should observe the patients closely without leaving during the operation. Turn off the power supply and remove the electrodes when necessary to ensure the safety of patients.
- Prevent the patients from contacting the other parts of the instrument and other conductors except the electrodes.

⚠ **Warning: After operation:**

- Turn all functional status back to the initial status , then turn off the power supply.
- Remove the electrodes gently and do not pull the lead cable emphatically when removing the electrodes.
- Clear up the instrument and all accessories for the trouble-free operation for the next use.

⚠ **Warning:**

The maintenance and servings of this instrument should be performed by the experienced technicians. When there is any functional abnormality with this instrument, it should be clearly identified to prevent the instrument from running with fault.

⚠ **Warning:**

Do not make any modification to this instrument.

⚠ **Warning:**

Maintenance and servicing

- The instrument should be subject to the maintenance and servicing regularly (Once half a year at least)

- Since the electrocardiograph is a measurement instrument, the users should have it verified by the legal unit of measurement according to the << Verification Regulation of Electrocardiograph>>, and the verification cycle should not be longer than 1 year.

- The signal input/output ports (when needed to use) are only permitted to be connected with devices of Class I which is in compliance with the standard IEC60601-1, and the total leak current should be measured by the users to determine if it conforms with the requirement and can be used after connection.
- The electrical basic circuit and the list of parts are exclusively provided to the qualified maintenance stations and personnel confirmed by our company.

⚠ **Warning:**

Products treated after scrapped: the relevant packaging materials, depleted batteries and scrapped products are treated, please remember to follow local laws, the user dispose properly of the scrapped products and materials on the basis of the requirements of local laws, and to support them recovery separation work.

**The use of rechargeable batteries:**

⚠ **Warning:**

Improper operation may cause the battery becomes hot, fire, explosion, destruction or attenuation of the battery capacity. The use of Rechargeable battery (hereinafter referred to as "Battery"), please read these instructions carefully and use precautions.

⚠ **Warning**:

Polarity of the batteries can not be reversed, or could cause an explosion.

⚠ **Warning**:

Do not fire near the source or the environmental temperature exceeds 60 ℃ battery, do not heat the battery or thrown it into the fire.
Taken to avoid the battery by water splashes, do not drop the battery into the water.

⚠ **Warning**:

Don’t chisel into the battery with metal chisel, hammering, or drop the battery or use the other ways to damage the battery, otherwise it will create fat cells Heat, smoke, deformation or combustion hazard.

⚠ **Warning**:

When you find the battery leakage or emit unpleasant odors, please go away immediately. If the fluid leak into the skin or clothes on, immediately wash with water. If the electrolyte leakage and enter the eyes, do not rub the eyes, immediately with a clean water and see a doctor.

⚠ **Warning**:

Only authorized installation or maintenance engineer can open the battery compartment, replace the battery; and must use the same type of rechargeable batteries which our company's division to provide.

⚠ **Warning:**

When the battery lifetime to reach, or find the battery, smell, deformation, discoloration or distortion, you should stop using the battery, And used batteries according to local regulations for processing.

⚠ **Warning:**

You must turn off battery before plugging; otherwise it will appear black and white, hang and so on.

**Note:**

**Taken to avoid the equipment being splashed with water.**

**NOTE:**

**In this manual, the subsequent amendments (not including the corrections) or revised editions of the dated reference documents are not applicable to this manual, and the latest versions of the reference documents not dated apply to this manual.**

**Warranty:**

**For product warranty issues please refer to that "warranty cards" were provides the content in accompanying document, if you have any questions, please call our customer service consulting, customer service hotline: 800-830-6643.**

### Maintenance Warranty

Our company guarantees the new instrument on the material and technological qualification for this product within 2 years since purchasing day, while accessories and consumables are not covered by the guarantee in principle. This guarantee is also inapplicable to the products undergoing any modification, disassembly, refitting or self-repairing without permission of our company, as well as the products damaged by accidents, fire disaster, thunder and lightning, flood and other disaster, intentional damage, improper installation and improper usage.

★ **Matters need attention on electromagnetic compatibility (EMC)**

This instrument conforms with the IEC60601-1-2, a safety standard for medical electronic devices or systems. However, the electromagnetic environment exceeding the limit or level defined by the standard IEC60601-1-2 will introduce the unwanted interference to the instrument, disable its intended functions or compromise its intended performance. Thus, if there is any discrepancy with this instrument compared to its intended functions during operation, please do not use it for longer until the adverse affect is identified and eliminated. The appropriate preventing measures are given below by this manual for the such cases:

- Affect from radiated electromagnetic wave:

The use of mobile phone may affect this instrument. Do instruct all the people around to turn off their mobile phone or mini-radio devices when any medical electronic device is installed.

- Affect from shock and conductible electromagnetic wave

The high frequency noise produced by other devices can be introduced into this instrument through the alternating current socket. Please identify the noise source first, and if possible, stop the working of related devices. If they are not allowed to be stopped, measures such as application of noise abatement device should be taken to minimize the influence.

- Affect from static electricity

The static electricity in a dry environment (indoor) may affect this instrument, especially in winter. Humidifying eh indoor air or pre-discharge the static electricity on the cable and the electrocardiogram recording personnel prior to using this instrument.

- Affect from thunder and lightning

If there is thunder and lightning occurring around this instrument, a voltage shock may be caused in this instrument. If it is considered as dangerous, you can pull off the plug of power supply from the alternating current socket to run this instrument by its internal power supply.

# Chapter 2. Safety Matters Needing Attention

★ **Please read this operation manual closely to learn the correct operation manners thoroughly for sagely and effectively using this instrument.**

**Note:**

This instrument should be installed on a smooth and stable working bench, and be prevented from the intense vibration and shock when moving it.

**Note：**

The frequency and voltage of the alternating current should meet the requirement, and the current capacity should be sufficient.

**Note:**

When the integrity of the protective wire is unsure, please use the internal DC power supply.

**Note:**

The applied part of circuit works in a floating ground condition, and the design conforms with the safety standard for Type CF, thus it is able to record and display the electrical signal of body surface generated by the activity of cardiac, but can not directly act on cardiac.

**Note:**

For the accuracy of the electrocardiogram tracing, this instrument should be installed in a quiet and comfortable environment.

**Note:**

Turn off the instrument immediately if there is any abnormality occurring during the operation.

⚠ **Warning:**

The power supply cable should be 3-core cable when using this instrument with the alternating current; otherwise the hazards of electric shock may be introduced to the patients and operators. When the available 3-core cable is unusable, please use the battery for power supply.

⚠ **Warning:**

The room should be equipped with the complete power supply system and grounding system, otherwise it might be harmful to the patients.

⚠ **Warning:**

When it is used in combination with the cardiac defibrillator, the contact with patient or hospital bed should be avoided. All the electrodes which are connected or unconnected to the patients as well as the patients themselves are not necessary to be grounded .All the electrodes for use should be the Ag-Cl electrodes provided by our company . The patient cable specially provided by our company should also be used for ensuring the protection against the charging of the cardiac defibrillator. It is not recommended to use this instrument in combination with the other electric stimulators. However, if necessary, they should be used in the presence of professionals and under the appropriate directions. When the instrument is used in combination with the cardiac defibrillator or the other electric stimulators (such as HF surgical units), it is recommended to use the disposable chest electrodes in the shape of plate to prevent the adhesive metal electrodes from burning the skin of patient.

⚠ **Warning:**

Be cautious when the patient is connected with more than one instrument, because the total leak current may be harmful to the patient. Only the Class I devices in compliance with the standard of IEC60601-1 are allowed to be connected to this instrument, and the total leak current should be measured by the users to determine that if it meets the requirement and can be used after connection.

⚠ **Warning:**

When the patient is connected with a cardiac peacemaker, the accuracy of ECG testing and the analysis result might be affected. In this case, it is recommended for physicians to perform the identification and analysis in combination with the waveform. However, the potential risk will be increased in this case. Thus it should be given particular attention to the safety problem when recording the ECG in this case, and the appropriate measures should be taken to ensure the leak current at a acceptable level.

⚠ **Warning:**

Keep the high frequency electric knife away from the electrodes to prevent the patients from burning. Make the electric resistance between the high frequency electric knife and patients' body as low as possible, and be cautious particularly. If necessary, the plate electrodes can be used because of its larger contact area to limit the high frequency current density into an acceptable range.

| | |
|---|---|
| ⚠ | **Do not use this instrument in presence of inflammable gas such as anaesthetics , oxygen, hydrogen or in presence of inflammable chemicals, otherwise it may cause the explosion or fire disaster.** |

| | |
|---|---|
| ⚠ | **Do not use this instrument in the medical hyperbaric chamber, otherwise it may cause the explosion and fire disaster.** |

| | |
|---|---|
| ⚠ | **Especial intention:The cardiac defibrillazing &monitoring unit not exit in this instrument, you must use our company's lead lines which has the electric defibrillation function.** |

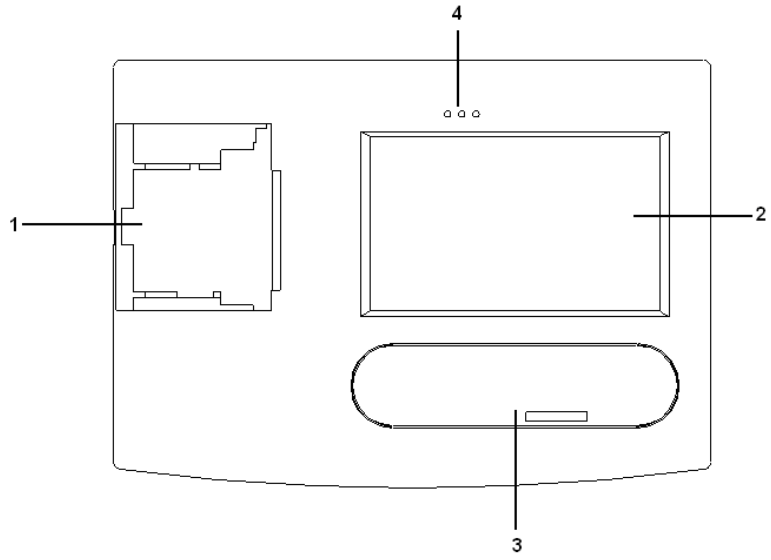
# Chapter 3 Features and Operating Principles

## 3.1 Composition of the Product:

Composition of the product: the product is mainly composed of the main machine, leads, limb electrodes and breast electrodes.

## 3.2 Appearance Description of the Product

- Description of the Front Structure of the Product




**1. Recorder**

Install record paper and realize printing and output.

**2. Display**

LCD part, used to display the working status (or waveforms) of the product.

**3. Control Panel**

The controlling area of the product, through which the operator can conduct operations and controls on the product.

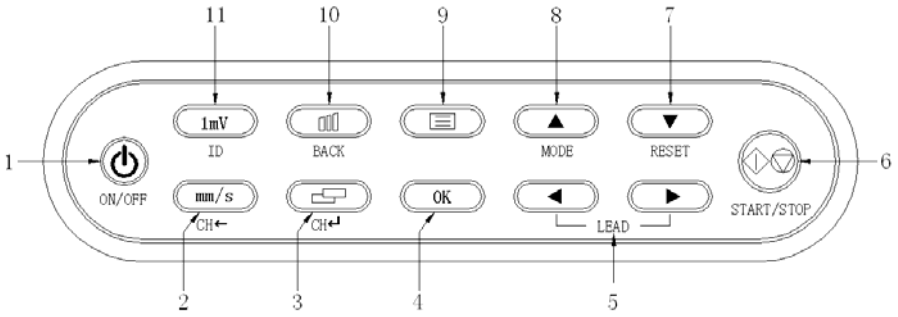
**4. Indicator Lamps**

Indicate the working status of the product. The functions of the lamps are as follows (from left to right): AC Working Indicator Lamp, DC Working Indicator Lamp, Charging Indicator Lamp.

**Note:**

**Do not put heavy objects on the LCD display or impact it, otherwise it may be damaged.**

- Description of the Various Function Keys on the Control Panel

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**1. ON/OFF** Controlling Button to Turn the Machine On and Off.

Used to switch the status of the machine between On and Off. When there is any malfunction or breakdown of the system, press this button and hold it for 3 seconds, and the machine can be turned off.

---

**2. mm/s(CH←)** Recording speed control button/ character deleting button

① Change the recording speed of the recorder according to the requirements of the applications.

② In the Chinese Bopomofo input method, delete the currently input letter.

---

**3. (CH↵)** Copy button/Character confirmation button

① When the recording is finished, conduct the last time of data copying before the machine turned off.

② In the Chinese Bopomofo input method, confirm the currently input letters.

---

**4. OK** Confirm Button

Confirm the selection of the options in the menu (or enter into the next level of menu).

---

---

**5. LEAD（◀/▶）** Lead switching button

① In the recording status, used to switch the lead;

② In the menu setting status, used to select the parameters of setting.

---

**6. START/STOP** Recording start/stop control button

In various recording modes, used to start or stop recording.

---

**7. RESET（▼）** Closing button (▼)

① In the standby status, used to close the lead signal;

② In the menu setting status, used to select options in the menu.

---

**8. MODE(▲)** Mode switching button (▲)

① Used to switch among various recording modes;

② In the menu setting status, used to select options in the menu.

---

**9.** Menu setting button

Press this button in the standby status to enter the menu, and in the menu status to exit the menu.

---

**10. (BACK)** Sensitivity switch/return button

① Conduct sensitivity switch in the standby status;

② In the menu setting status, used to return to the upper level of menu.

---

**11. 1mV(ID)** ID button

① In the recording status, press this button to promptly print the ID sign;

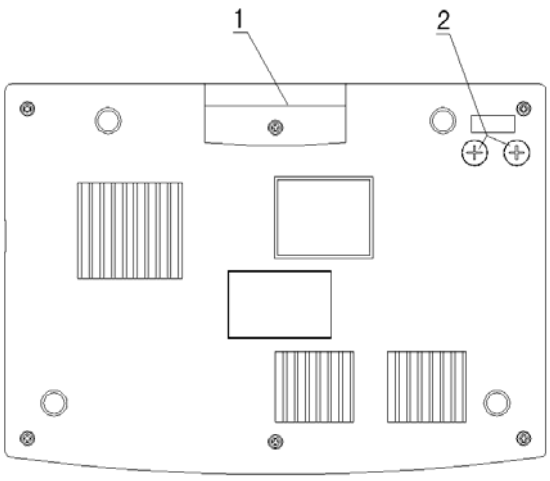
② In the standby status, press this button to browse the information of the patient.

---

**Note:**

**Do not use sharp objects to operate the control panel in order to prevent damaging the panel, being shocked by contacting the internal circuit or damaging the product. Do not put irrelevant objects on the control panel for a long time, because that will reduce the elasticity of the control buttons on the panel and disable the panel functions.**

- Description of the Bottom Structure of the Product



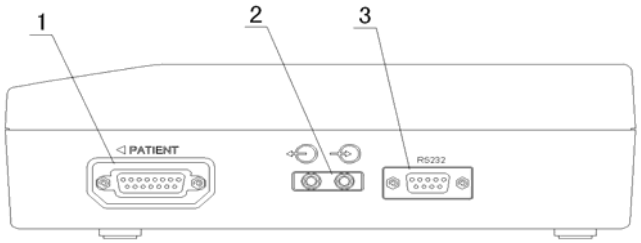

**1. Handle**

Used to carry the product.

**2. Fuse Base**

With fuse inside.

- Description of the Right Structure of the Product




**1. Lead Input Interface**

Connect to the lead.

**2. Line Input/Output Interface**

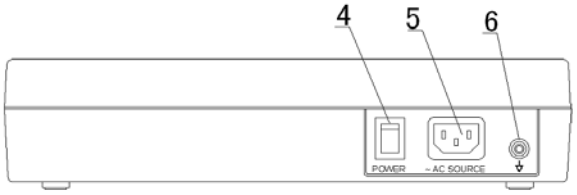
Line Input Interface: receives the input ECG analogue signals and conducts printing;

Line Output Interface: outputs the ECG analogue signals collected by the product.

**3. RS-232 Interface**

The data transmitting port to conduct communications with the computer.

- Description of the Rear Structure of the Product




**4. AC Power Supply Switch**

Used to connect and cut off AC power supply.

**5. AC Power Supply Socket**

Used to connect to AC power cord.

**6. Equipotential Point (grounding post)**

The equipotential connecting point when the equipment is used in connection with other facilities, also the safe grounding point of the product.

## 3.2 Principle introduction and block diagram

### 1. Power supply

(1) Principle introduction about power supply

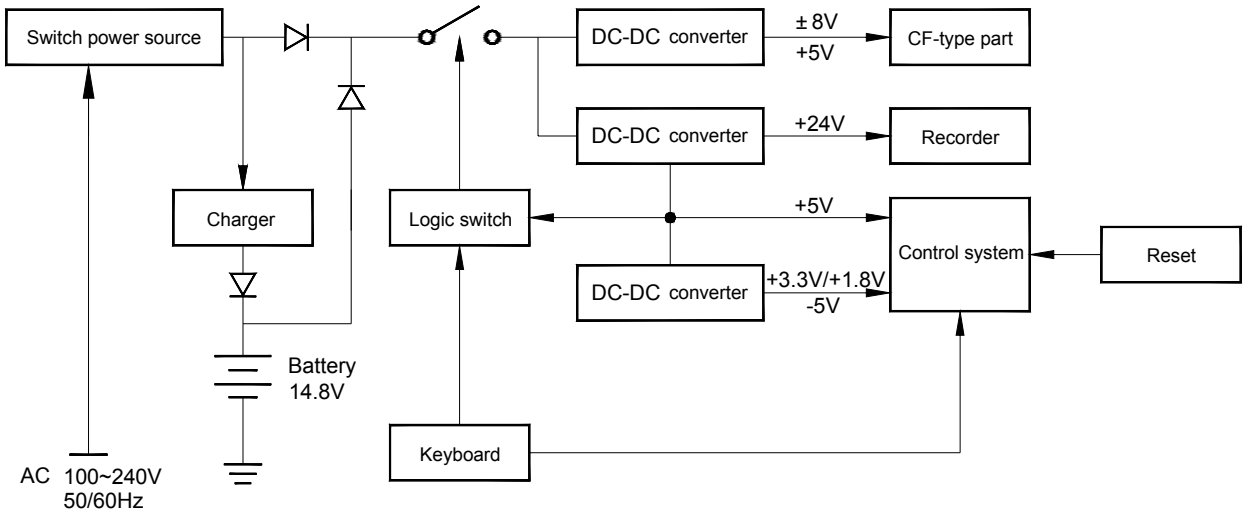
The alternating current can be transformed to be the direct current with a voltage of about 20V through the voltage transformation or the switch power transformation. Thus the internal rechargeable battery can be charged with stable voltage and limited current. At the same time, the transformed current together with the battery output can be transmitted to DC /AC switch circuit ,then transformed to be the main power supply as +5V and +24V by the switch power stabilizer, and transformed to be +3.3V、+1.8V and -5V through the power supply transformation.

The power supply with the voltage of +5V,+3.3V、+1.8V and -5V is supplied for the ground circuit. The normal current load is 750mA approximately, the designed capacity is 3A, and the current limiting reaction is at 3.75A.

+24V is for the paper driving unit and the printing head. The power supply to the paper driving unit is in a manner of width adjustment and wave chopping to enhance the efficiency of the driving unit. The normal current load is 500mA for the +24 power supply, the designed capacity is 850mA and the current limiting reaction is at 1.2A.

The power supply for the floating ground circuit is from the output of AC/DC switch circuit which is transformed by the self-excited switch power and the insulation pulse transformer. The +5V power supply for digital part in the floating ground circuit is from the direct output of switch power with invariable voltage, and the normal current load is 150mA with the designed capacity of 300mA. The +8V and -8V supplied for analogue part of the floating ground circuit is from the variable voltage output of the switch power which is transformed by the three terminal stabilizer, and the normal current load is 60mA with a designed capacity of 100mA.

(2) Block diagram for the principle of power supply (This electrical basic circuit diagram and the list of parts are exclusively provide to the qualified maintenance stations and personnel conformed by our company)



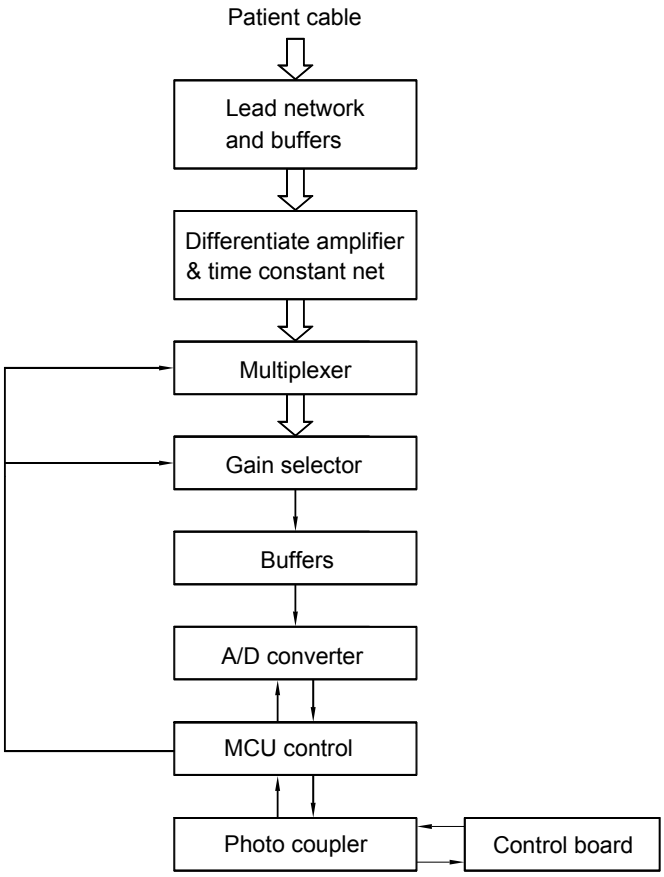
## 2 Amplification

(1) Principle introduction for the amplifying unit

The floating ground circuit of the whole instrument is a signal capture system which consists of analogue circuit and A/D converting system. The analogue circuit is composed of lead signal amplifier, anti-aliasing low-pass filter, channel switch, gain controller, lead-fail detector, etc. The CPU system of the whole instrument is responsible to coordinate the various circuits such as A/D converter, channel switch, gain controller and lead-failure detector to perform the signal capturing and lead-fail detecting. The control information between the floating ground and ground circuit and A/D converting data is transmitted by the photocoupler.

The sampling rate for lead signal is 1000/960Hz, while the sampling rate for lead-fail signal is 100/120Hz, and the cut-off frequency for anti-aliasing low-pass filter( -3dB) is 200Hz. The sampling rate conforms with the standards of AHA (American) and CSE (European) which require that the sampling rate of electrocardiograph with the analysis function should be no less than 500Hz. The anti-aliasing low-pass filter can limit the input bandwidth of A/D converter while ensuring the wanted signal bandwidth to avoid the signal aliasing caused by the sub-sampling of high frequency signal.

(2) Block diagram for the amplifying unit

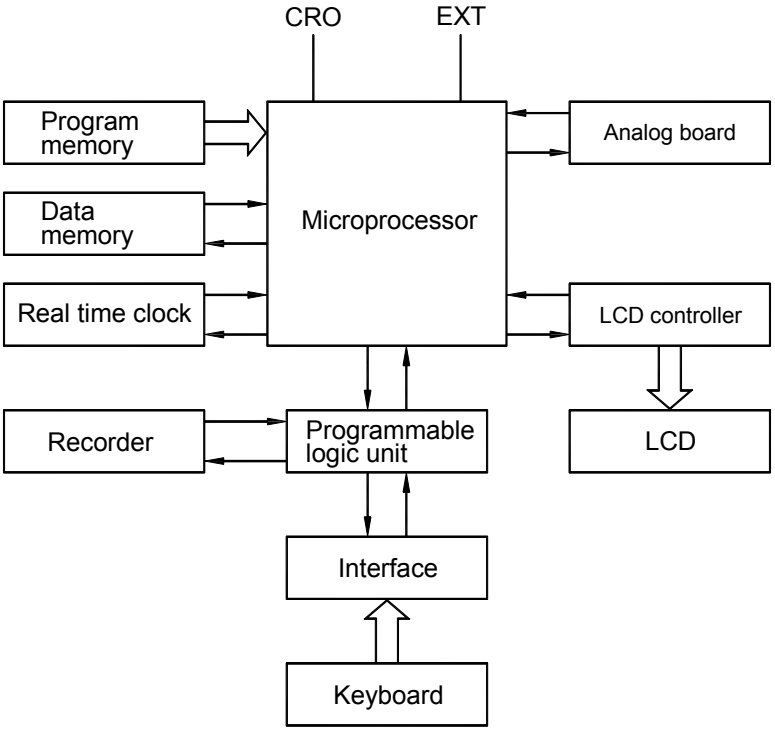


## 3 Controlling

(1) Principle introduction for the control unit

The control system is composed of printing controller, keyboard controller, liquid crystal controller and CPU system, etc. The lead signal acquired by the signal capture system is transmitted by the high speed photocoupler to the CPU system, then subject to the processes of digital filtering, gain controlling and printing driving, finally transmitted to the printing controller to perform the printing of the waveform. After printing, the waveform will be measured, analyzed and processed by the CPU system. The CPU system can also receive the interrupt signals and the key coding from the keyboard to perform the key interruption processing. In addition, such functions as lead fail detection and paper compartment empty detection, battery voltage control, automatic turning off the power supply, CRO analogue output, sampling and printing for EXT input are all administrated by the CPU system. The keyboard controller produces the keyboard scanning signals to perform the processing of key-jitter elimination, then the key coding and the interrupt signal is received and processed by the CPU system. The liquid crystal controller is responsible to the data and commands from the CPU system to perform the displaying the control status of the whole instrument.

(2) Block diagram of the control unit



# Chapter 4 Preparation before Operation

## 4.1 Location selection

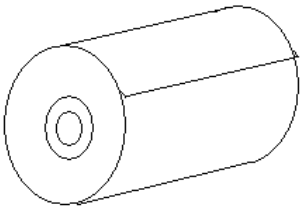
ECG-101G is not to be limited to be used in hospitals and clinics. Because of the portable feature it can be used anywhere with the battery. It is applicable to outdoor occasions such as group examination.

The following aspects should be considered when selecting the location to install this instrument to recording the electrocardiogram accurately:

- Keep the instrument and the bed for testing away from the high voltage cable. The substantial radiation source around this instrument may introduce the noise interference to this instrument.
- Keep this instrument away from devices such as X-ray, ultrasound, radio machines and fluorescence light because they are probably the substantial radiation sources.
- Please use this instrument with the ambient temperature of 5℃~40℃.
- Please use this instrument with the ambient humidity of 30%~80% (without condensation).

## 4.2 Loading of the recording paper

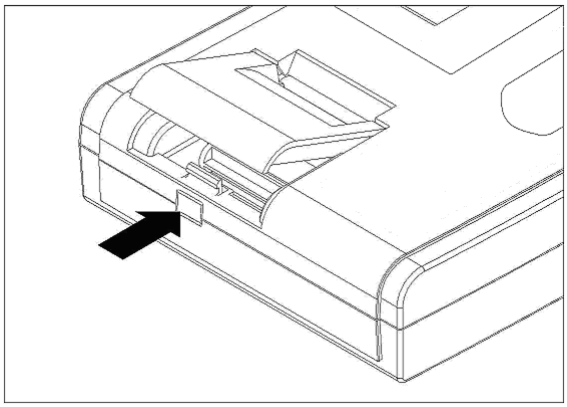
ECG-101G can use the standard roll paper (63mm)



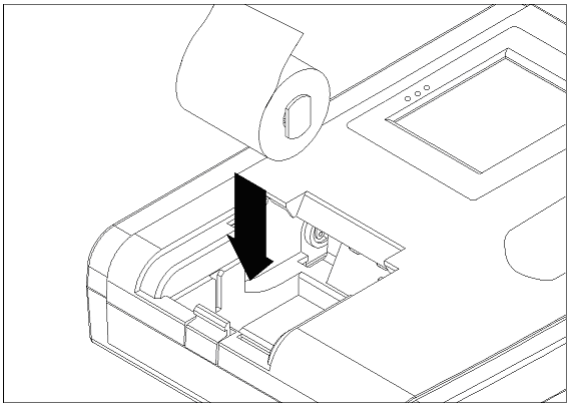
**Thermal recording paper—roll paper-63mm**

The product uses thermo-sensitive paper as the recording media. In order to get clearly printed information, it is recommended to use the recording paper provided along with the product or purchase the same type of recording paper from the company. As the thermo-sensitive material is only sprayed on the front face of the recording paper, so the direction of the recording paper must be correct during installation, otherwise the printing cannot be realized. The installation sequence of the recording paper of the product is explained below:

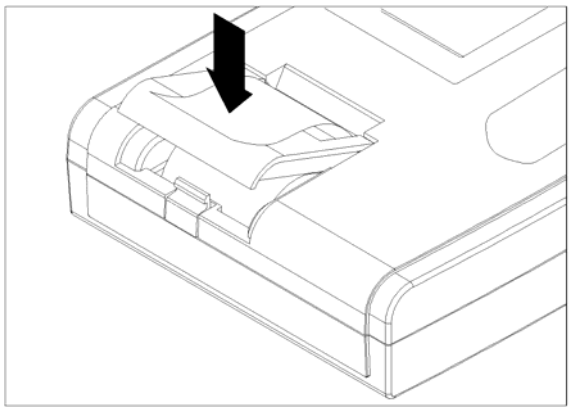
a. Press the button at the position pointed by the arrow in the figure below to make the paper cartridge cover jump up and then remove the paper cartridge cover;



b. Install the paper reel into the paper barrel in the direction indicated in the figure below, and put the paper barrel with recording paper into the paper cartridge and pull out a section of recording paper by 6cm in length. Please be aware that the end of the paper reel with a positioning pin must be installed into the corresponding clamping position in the paper cartridge.



c. Align the gear on the paper cartridge cover to the gear position on the paper cartridge, and press the end of the paper cartridge cover to lock it.



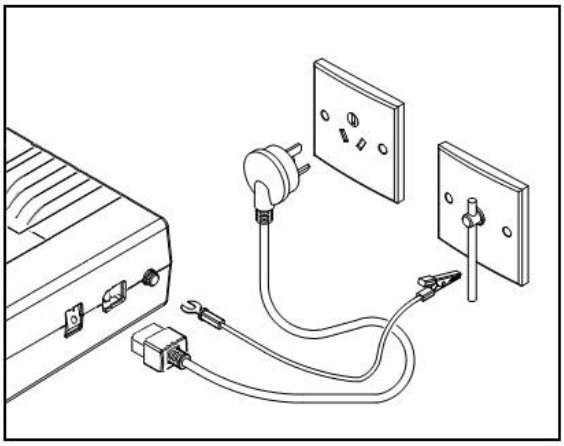
**Note:**

**The product has a paper out warning function. When the printing paper in the paper cartridge has been used up, the display interface of the product will appear warning information (please refer to the chapter of "Warnings of the Product"). If the recording paper has not been properly installed, the product would not find the recording paper, and the paper out warning would not appear, then the installation of recording paper should be checked.**

## 4.3 Connection of the power supply

**1) Using the AC power supply**

When the product uses AC power supply to work, firstly turn the AC power supply switch at the back of the product to "○"position, and connect the opening end of the grounding wire to the grounding post of the product, and then connect the other end of the grounding wire with crocodile clips to the dedicated grounding point in the working environment. This kind of grounding connection must be reliable, otherwise just use the AC power supply to charge the battery of the product, and not directly use the AC power supply to run the product on patients. When the grounding line is properly connected, insert one end of the power cord provided along with the product to the AC input terminal of the product, and the other end (plug) to the network power supply socket, as shown in the figure below.



When this instrument is used with other medical devices, please use the external grounding cable provided together with this instrument. Connect the grounding terminal of this ECG with the same grounding terminal of the other devices to prevent the patient from the electrical shock. When there is any leak current with the other devices, this connection will induce it into the ground for protection.

**2） Using the battery**

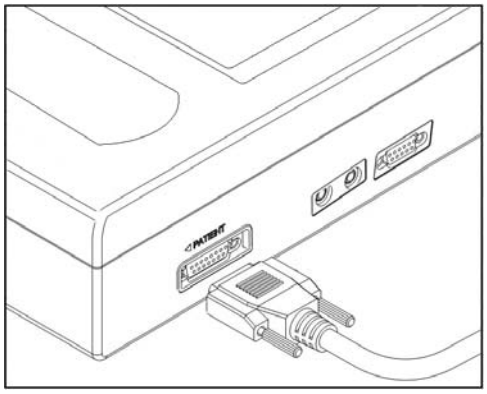
When the battery is required to be used as a power supply, the built –in rechargeable battery can be used without loading by users. Please check the capacity and status of the battery before use it.

**Note:**

**The reliability of grounding for this instrument can be enhanced by connecting one end of the accessorial grounding cable onto the grounding column of the instrument while connecting the other end to the ground. Do not use the water pipe or the other pipes as a grounding cable, or else the safety protective measure of first level of this instrument is ineffective, and the patients might be in danger of electrical shock.**

## 4.4 Connection of lead lines

The connecting position on the product to the lead is shown in the figure below. When the plug of the lead is fully inserted into the lead socket of the product, turn the two fastening bolts on the lead plug to lock the lead onto the product and prevent loosing.



**Note:**

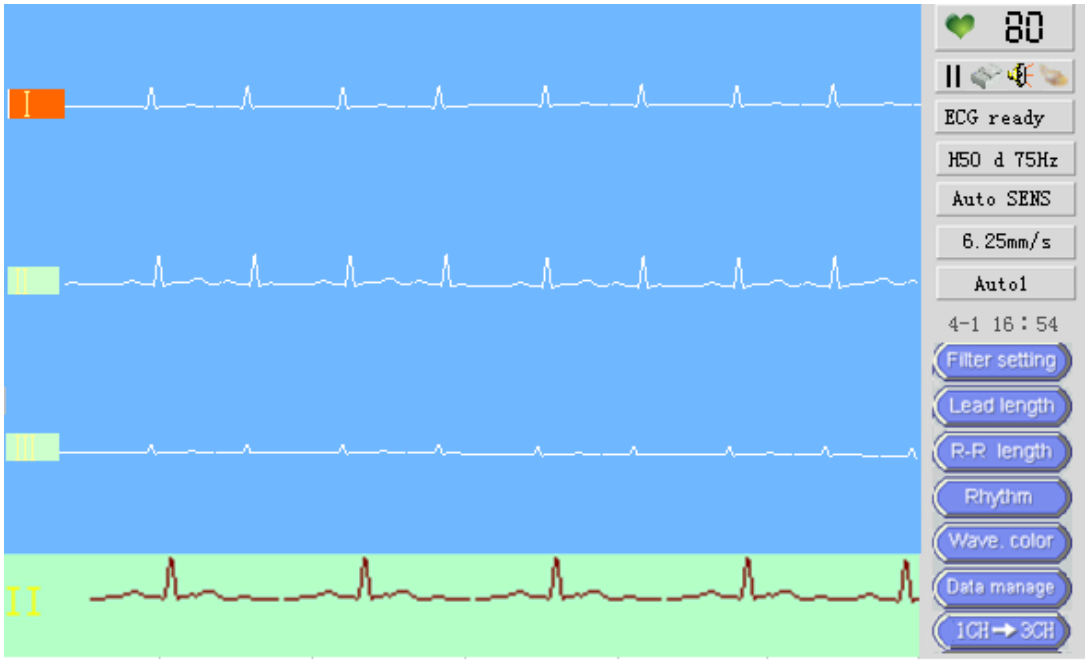
**Please use the lead provided along with the product, otherwise the working efficiency of the product may be degraded and the product may be damaged.**

## 4.5 Start the instrument

As the flowing picture, press the operating button of ON/OFF (ON/OFF), the power supply indicator light will light and the instrument turns to be in a initial status,

LCD displays the following screen:

When the instrument enters into the system and the following initial picture is displayed on the LCD screen, it indicates that this instrument has entered into the stand-by status and you can start operating.



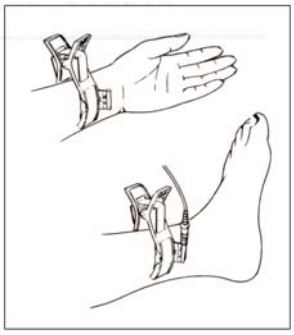

## 4.6 Connection of electrodes

The connection of electrodes is critical for the accuracy of electrocardiogram recording, thus please make sure the contact condition of the electrodes is good .New and old electrodes, as well as the reusable and the disposable electrodes may not be used simultaneously. If used, the quality of the recorded electrocardiogram may be affected to a large extent. The electrodes and lead plugs are not allowed to contact the other

surface or conductor such as the metal bed. If the electrodes replacement is needed, please replace all the electrodes for once.

**1) Electrodes connection onto limbs**

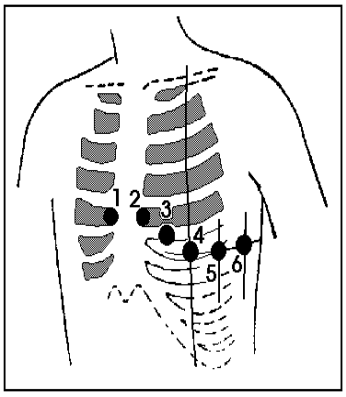
The eletrodes for limb should be connected onto the soft skin of the limbs. Clean the skin for electrodes connection with the medical alcohol first, then coat it with a little electrodes cream. The electrodes for limbs should be connected as follows( see the following picture):



R (RA) Connected onto the right hand
L (LA) Connected onto the left hand
RF (RL) Connected onto the right leg
F (LL) Connected to the left leg

**2) Electrodes connection onto chest**

Clean the skin of chest for electrodes connection with the medical alcohol. Coat the electrode cream on these sites in a diameter of about 25mm as well as the edge of adhesive plates of the electrodes. Compres the suction bulb of the chest electrodes to make the chest electrodes adhere to the V1~V6 sites.The chest electrodes should be connected as following picture:




C1 (V1) : 4th intercostal place at the right margin of the sternum.
C2 (V2) : 4th intercostal place at the left margin of the sternum.
C3 (V3) : Midway bettwen C2 and C4.
C4 (V4): 5th intercostal place at the left mid-clavidular line
C5 (V5) : At the horizontal leve lof C4 , at the left anterior axillary line
C6 (V6) : At the horizontal level of C4, at the left mid-axillary line

**Note:**

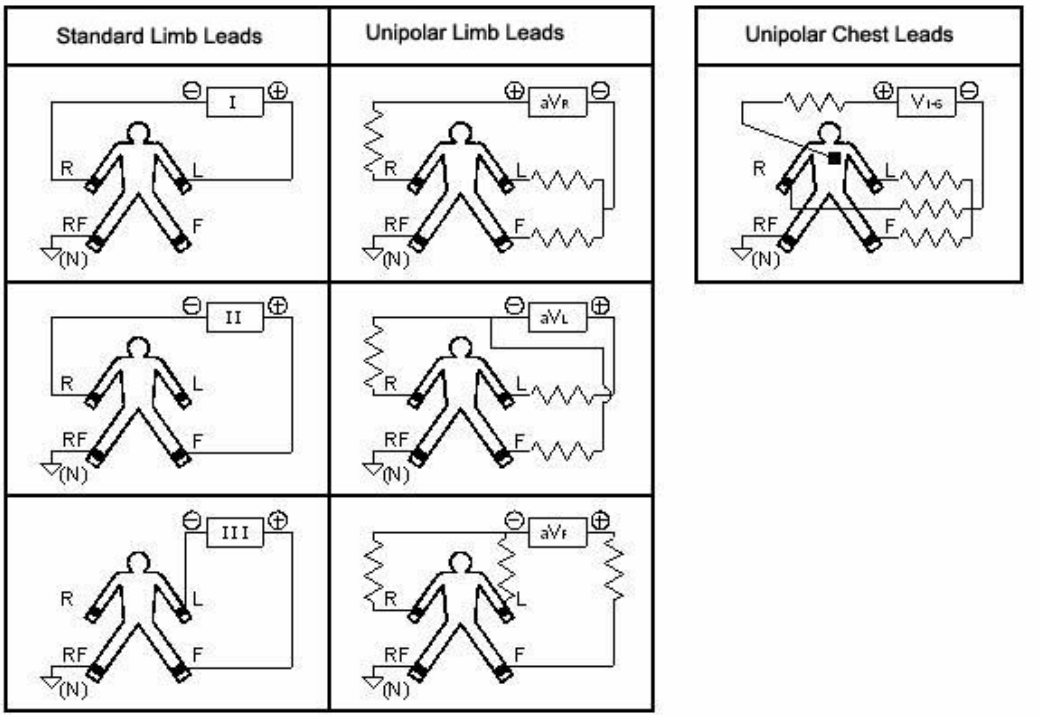
**The electrodes cream should be coated separately, and please prevent the electrodes from contacting each other to avoid the short circuit. If the electrode cream is not available , the ECG test should be performed for a short term as follows: Clean each site for electrodes connection with the 75% alcohol , then conect the elctrodes onto them immediately to ensure the electrodes contacting sites with a proper humidity. Do not**

**replace the electrode sream with the physiological saline or else the electordes might be corroded.**

- **Comparsion tale between the line color and the corresponding eletrodes**

| LEAD | | European standards | | American Standard | |
|---|---|---|---|---|---|
| Sites for electrode | Lead line color | Symbol for electrod | Color code for electrod | Symbol for electrod | Color code for electrod |
| Right arm | Gray | R | Red | RA | White |
| Left arm | Gray | L | Yellow | LA | Black |
| Right leg | Gray | N or RF | Black | RL | Green |
| Left Leg | Gray | F | Green | LL | Red |
| Chest 1 | White | C1 | Red | V1 | Red |
| Chest 2 | White | C2 | Yellow | V2 | Yellow |
| Chest 3 | White | C3 | Green | V3 | Green |
| Chest 4 | White | C4 | Brown | V4 | Blue |
| Chest 5 | White | C5 | Black | V5 | Orange |
| Chest 6 | White | C6 | purple | V6 | purple |

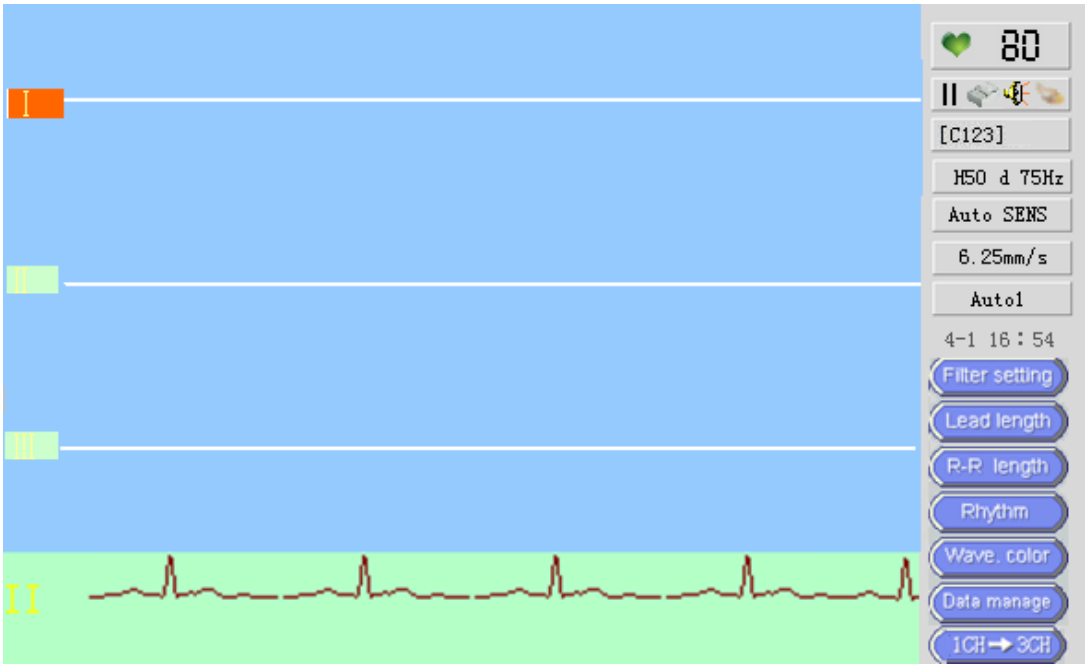
■ **Lead modes and system diagram**




## 4.7 Indication for lead fail

This instrument will check the lead connection all along, and if the lead fail is detected, the detached lead line code willl be displayed in the approriate lead position.

The screen will display the following picture:




If the lead fail occurs, the approriate waveform will not be displayed, and the “record” button is ineffective. The users should reconnect the electrodes or electrodes lead based on the given information for the detached electrodes or the electrodes lead.When the

lead lines failed off, it will no longer to analysis the wave, and the print report display “lead is disconnected, cannot be analyzed”.

**Note:**

**1. [*]:**

**① When the lead line with the patients or host is not reliable connectivity, ECG can not correctly send, that “*” of the symbols is displayed to warn , "*" indicates the current lead;**

**② when polarization voltage is over specified value of equipment, the symbol is displayed to warn.**

**2. In the course of use, “*” of the symbols is displayed to warn the screen, to dealt with according to the following approach:**

**① Press "lead shutting off " button to intervene manually, to eliminate the effects of strength exceeds the value of the polarization voltage on the amplifier products, will enable amplifiers rapid return to normalcy;**

**② Press "lead shutting off " button to intervene manually, still can not lift a state of alert, they should double-check the connection of the corresponding electrode and the skin of patient , the electrodes and l the lead lines or host of is reliable, when such a reliable connection, the state of alert lifted.**

# Chapter 5 Operation Procedures

## 5.1 Inspection before Operation

- Is the grounding connection correct?
- Is the grounding wire complete?
- Is the grounding wire connection normal?
- Is the grounding bolt is tightened?
- Is the connection between the grounding wire joint on the wall and the grounding wire correct?
- Is there any electrical equipment which may introduce the radio-frequency or the power supply interference such as X-ray, ultrashort wave device around this instrument? If there is , they may introduce the interference to the ECG instrument. If necessary, please turn off these equipment or perform the test in another location without interference.
- Is the ambient temperature and humidity in compliance with the requirements for using this instrument?
- Is the connection of power supply cable good? Or is it intertwisted with other cables?
- Is the connection of lead lines good? Or are the lead lines close to the AC power supply cable?
- Is the connection between the lead line pins and appropriate electrodes correct?
- Is the connection of electrodes good?
- Is the electrode contacting skin of the tested patient subject to the appropriate pretreatment?
- Have the electrodes been contaminated? If they have, please remove the stains with the alcohol and the soapsuds.
- Is the connection of electrodes too loose? If it is, please tighten them.
- Are the new and old electrodes used together?
- Is there any contact between different electrodes (particularly in the chest area)
- Is the tested patient too nervous? If he (she) is, please explain to the patient that the ECG test is a simple process without any harm to the patient to relax him (her).
- Is the tested patient acting or speaking?

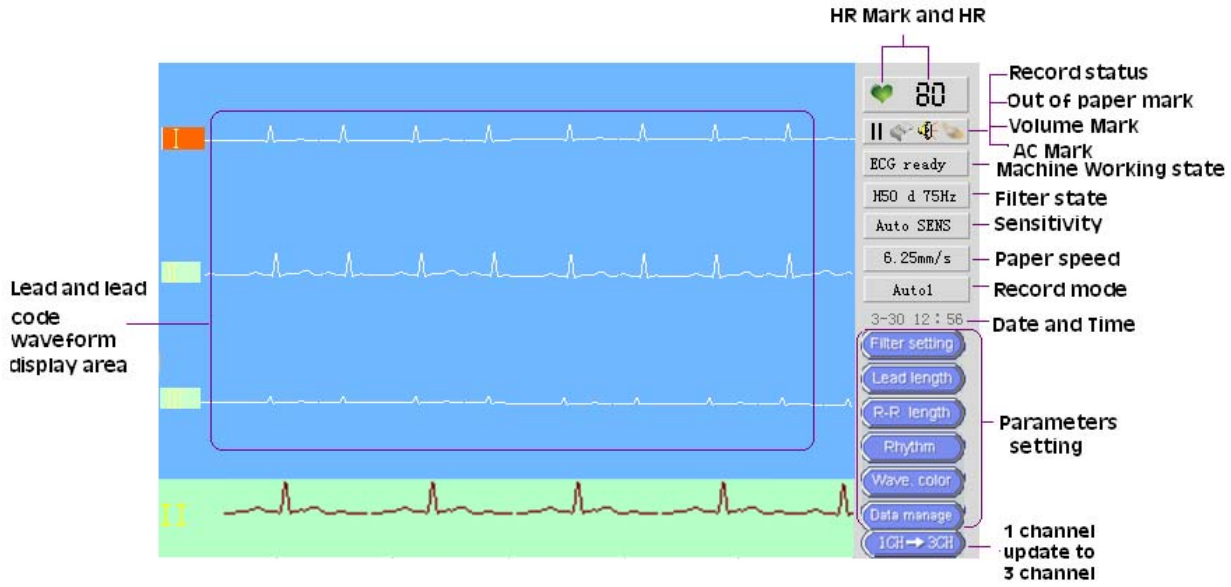
- Is the bed too narrow for the patient?
- Do the naked parts of the patient body such as hand an foot contact the metal part of the bed? If they do, the AC interference may be introduced to the electrocardiogram tracing.
- Is the examination room comfortable?
- Is the quantity of the recording paper sufficient?

**Note:**

**For the safety of the examined patient and stability of the electrocardiogram recording, the above inspection should be finished before operation. Make sure all the conditions about the instrument and patient normal before electrocardiogram recording.**

## 5.2 Electrocardiogram recording screen

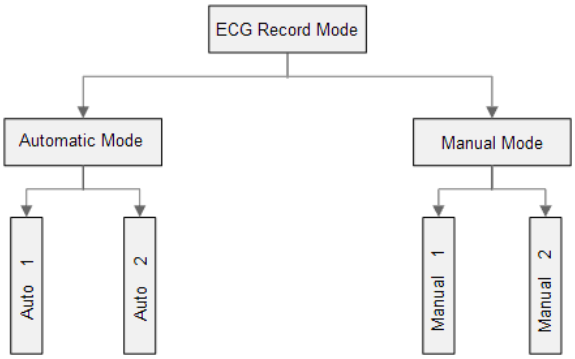
Start the instrument and make sure all the lead connection is correct, and then the electrocardiogram can be recorded. The following electrocardiogram recording screen will be displayed on the LCD:



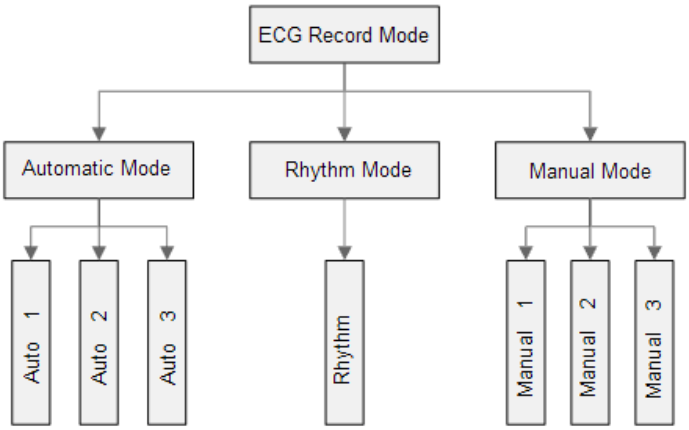

## 5.3 Electrocardiogram recording operation

To perform the electrocardiogram recording , Please choose a recording mode( operating mode) first .There are two recording manners as automatic recording and manual recording modes as the following picture:

**One channel:**




**Three channel:**



## ■ Functions and Features of the Product in Various Recording Modes

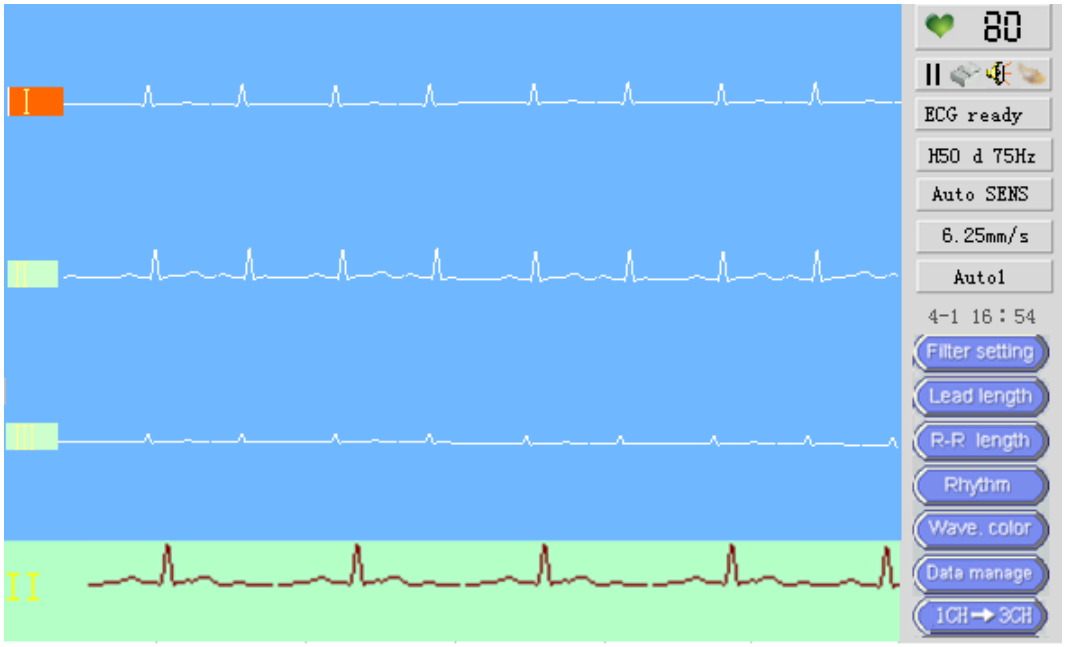
| Recording Mode | Description of the Functions and Features | Comment |
|---|---|---|
| Auto 1 | On the recording paper, only the signals of one lead can be recorded in each recording cycle in the longitudinal direction, and the lead can be automatically changed when each recording cycle is finished, and the waveforms of the signals of all leads are recorded in the transverse direction (for example: Ⅰ→Ⅱ→Ⅲ→aVR→ aVL→aVF→V1→V2→ V3→V4→ V5→ V6, 12 recording cycles in all), and then the results of automatic analysis can be printed or stored according to the operator's selection. | For 1 channel and 3 channel |
| Auto 2 | On the recording paper, the signals of two leads can be recorded in each recording cycle in the longitudinal direction, and the lead can be automatically changed when each recording cycle is finished, and the waveforms of the signals of all leads are recorded in the transverse direction (for example, the recording sequence when the rhythm lead selection is II lead is as follows: Ⅰ+Ⅱ→Ⅱ+Ⅱ→Ⅲ+Ⅱ→ aVR+Ⅱ→ aVL+Ⅱ→ aVF+Ⅱ→V1+Ⅱ→ V2+Ⅱ→ V3+Ⅱ→V4+Ⅱ→ V5+Ⅱ→ V6+Ⅱ, 12 recording cycles in all), and then the results of automatic analysis can be printed or stored according to the operator's selection. Among them, the second lead signal in the longitudinal direction is the selectable rhythm lead signal. | For 1 channel and 3 channel |
| Auto 3 | On the recording paper, the signals of three leads can be recorded in each recording cycle in the longitudinal direction, and the lead can be automatically changed when each recording cycle is finished, and the waveforms of the signals of all leads are recorded in the transverse direction(for example: Ⅰ+Ⅱ+Ⅲ→ aVR+aVL+aVF→ V1+V2+V3→V4+V5+V6, 4 recording cycles in all), and then the results of automatic analysis can be printed or stored according to the operator's selection. | Only for 3 channel |
| Manual 1 | On the recording paper, only the signals of one lead can be recorded in the longitudinal direction, the waveforms of the signals of the current lead are recorded continuously unless the lead is changed manually (for example: Ⅰ→ ……). | For 1 channel and 3 channel |
| Manual 2 | On the recording paper, the signals of two leads can be recorded in the longitudinal direction, one of them is the currently selected rhythm lead, and the waveforms of the current lead and rhythm signals are recorded continuously unless the lead is changed manually (for example, when the rhythm lead selection is II lead: Ⅰ+Ⅱ→ ……). | For 1 channel and 3 channel |
| Manual 3 | On the recording paper, the signals of three leads can be recorded in the longitudinal direction,, and the waveforms of the signals of the current leads are recorded continuously unless the leads are changed manually (for example: Ⅰ+Ⅱ+Ⅲ→ ……). | Only for 3 channel |
| Rhythm Analysis | ① Continuously display the signal waveform of the currently selected rhythm lead;<br>② Conduct data acquisition first according to the selected time of acquisition, and then evenly distribute (within the time of acquisition) the acquired signal waveforms in three lines of output, and print out the results of automatic analysis. | Only for 3 channel |

- Description of the Relevant Information on the Display and Recording Paper in Each Recording Mode(Information shown in the following diagrams may be different in different parameter settings of various options, so is for reference only)

**1) Automatic recording**

- **Auto1 (Automatic 1 channel)**

The default recording mode of this instrument when leaving factory is “Automatic 1 channel” The whole instrument work status will be displayed on the LCD screen as the following picture:




Observe that if the lead ECG waveform is stable in the rough from the displaying of heart rate. If necessary, press the RESET button of “lead shutting off” to stabilizer all the lead waveform instantly.

a, Press MODE button, you can choose other record mode ,such as "Auto 1 ","Auto 2 ","Manual 1 ", "Manual 2 ","Manual 3 "and "Rhythm”;

b, Press mm/s CH← button to choose the speed, There are 4 levels of recording speed provided by this instrument as :6.25 mm/s、12.5 mm/s、25 mm/s and 50 mm/s.

c. Press OK button, the parameter area appears red background, then select the filter settings, and press the ◄ ► LEAD button to change the filter state. There are 4 types of filter status provided by this instrument as : 0.05-150Hz、H50 d、H50 d 75Hz、H50 d 35Hz.

The following table is the detailed description about the various parameters in the filter setting:

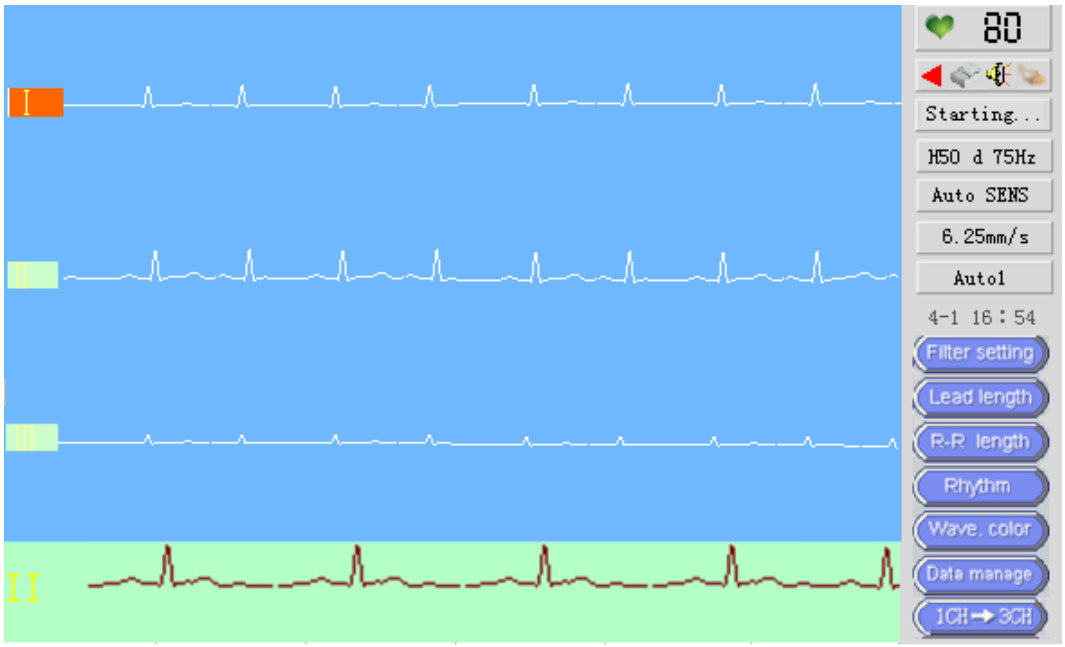
| Status or Control Items | Setting Value | Comment |
|---|---|---|
| Filter Setting: | 0.05-150Hz | All filters are off. |
| | H50 d | Only AC filter and drift inhibition（0.5Hz Highpass） are on. |
| | H50 d 75Hz | All filters are on, and the frequency of the myoelectrical filter is 0.5-75Hz |
| | H50 d 35Hz | All filters are on , and the frequency of the myoelectrical filter is 0.5-35Hz |

**Note:**

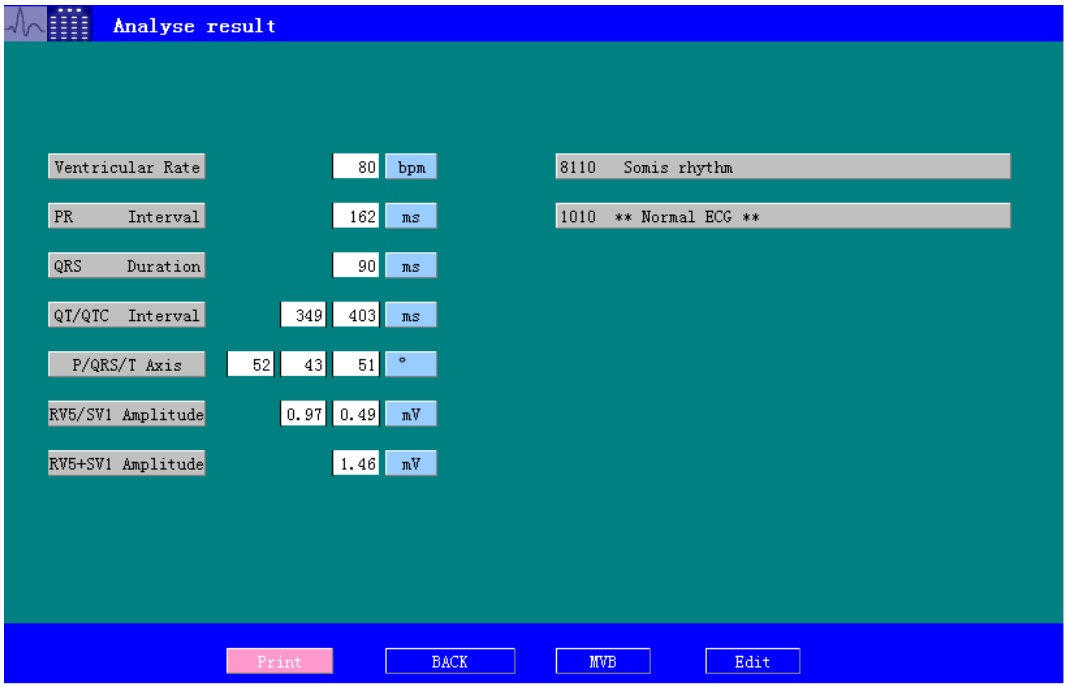
**The H50 in the H50 d 75Hz will be displayed varying with the set AC frequency. For instance , when the AC frequency is set to 60Hz, H60 d 75Hz will be displayed.**
**The default state of the flitter is 0.5-35Hz when boot scrap.**

d. Press

button (Starting /Stop button) to start recording. and the symbols of "◀", "II" indicate the acquiring/ recording status respectively . The leading code which is currently recorded will be displayed in the reverse type as the following picture:

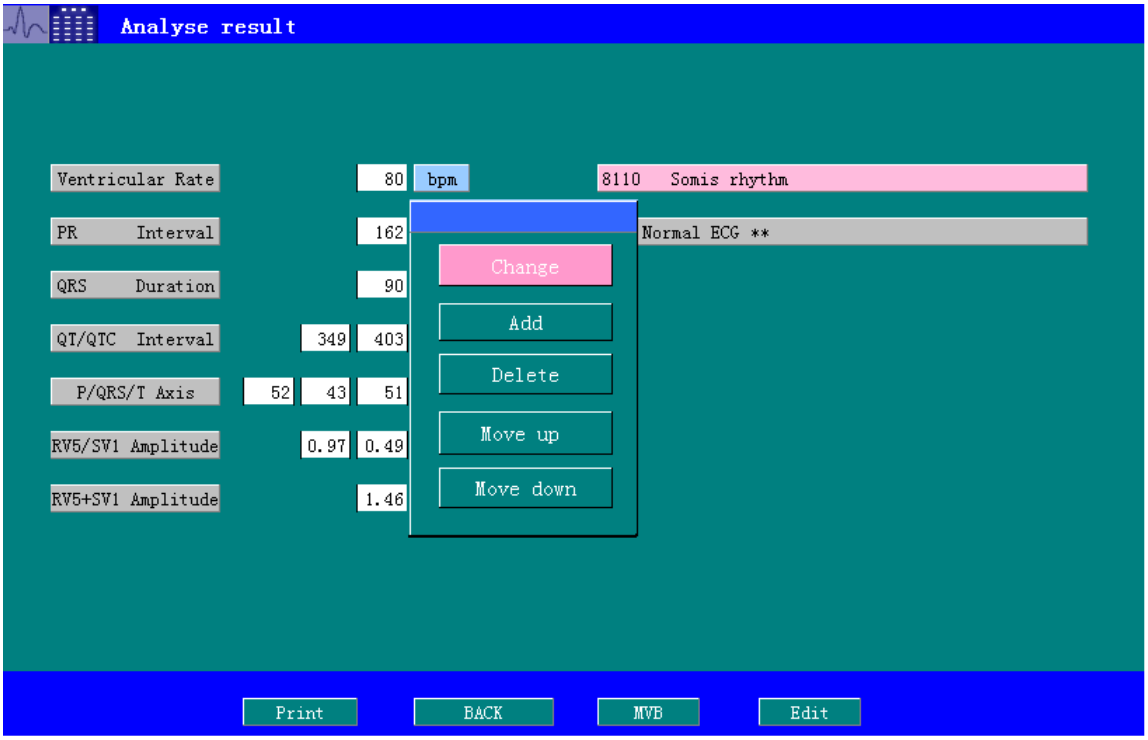



After the ECG recording, system will automatic analysis and storage, it will display the measurement result after analysis.



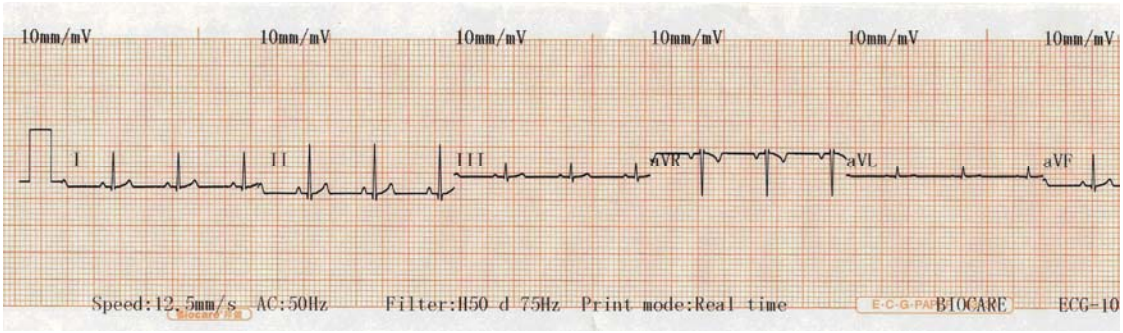
As shown above, in the measurement results interface, you can select "Print ", "Return"," MVB ","Edit "

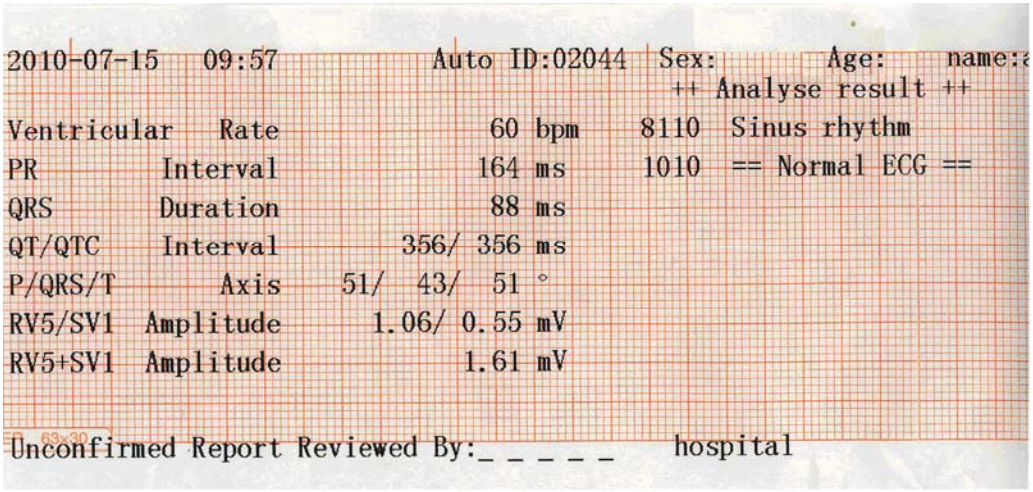
Press LEAD button to move the selection box to the "Edit ", then press the OK button, the report edit interface appears, as shown below:



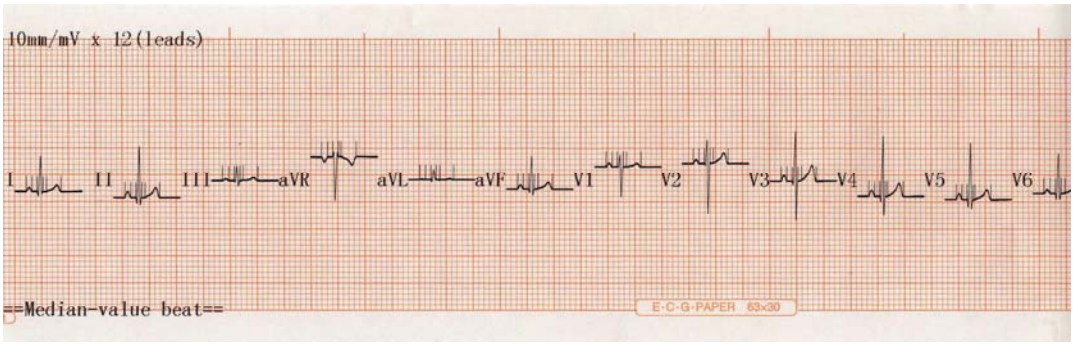

In the Report Edit interface, there are such functions: Change, Add, Delete, Move up and Move down. Specific operations please refer to Chapter 7 "ID input".

**One standard waveforms recorded Legend:**



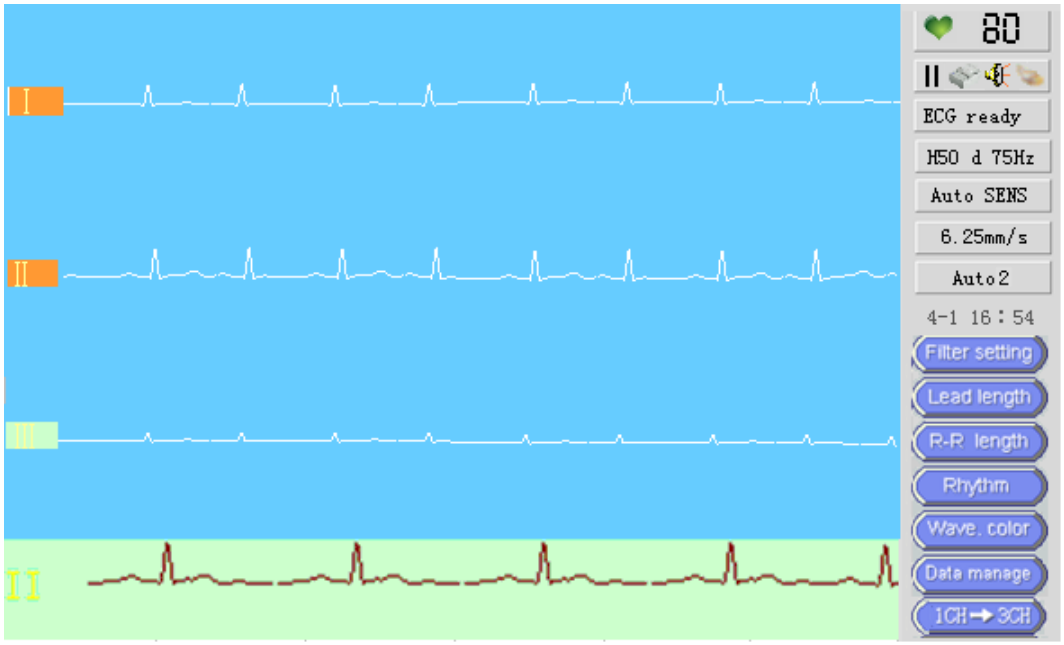

2010-07-15 09:57 Auto ID:02044 Sex: Age: name:
++ Analyse result ++
Ventricular Rate 60 bpm 8110 Sinus rhythm
PR Interval 164 ms 1010 == Normal ECG ==
QRS Duration 88 ms
QT/QTC Interval 356/ 356 ms
P/QRS/T Axis 51/ 43/ 51 °
RV5/SV1 Amplitude 1.06/ 0.55 mV
RV5+SV1 Amplitude 1.61 mV
Unconfirmed Report Reviewed By:_ _ _ _ _ hospital

**MvB**:




■ **Auto 2 (Automatic 2 channel)**

This mode is the automatic 2 channel, press the MODE button (Mode switching button) to select (Auto 2), LCD display the working status of machine, as shown below:



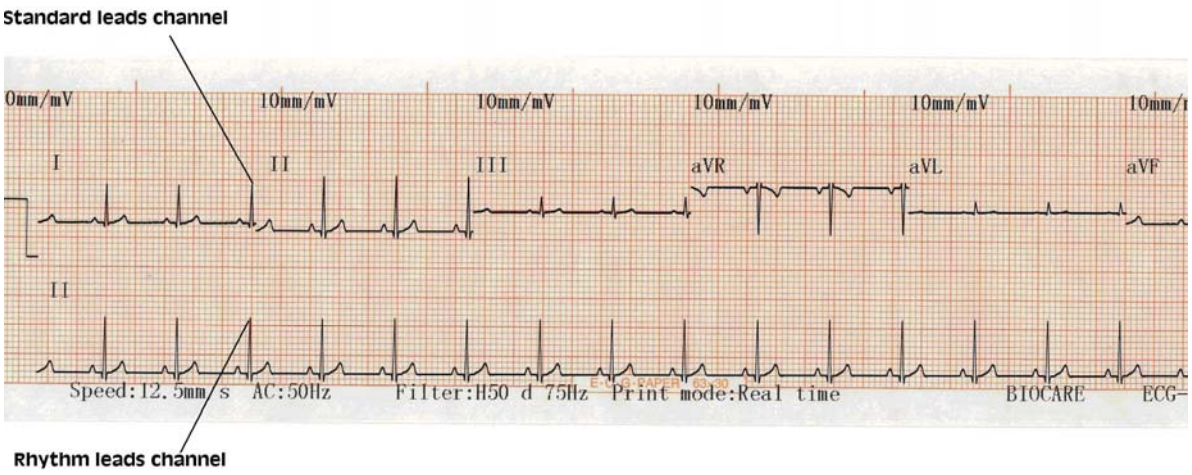
Observe that if the lead ECG waveform is stable in the rough from the displaying of heart rate. If necessary, press the RESET button of “lead shutting off” to stabilizer all the lead waveform instantly.

a, Press mm/s button to choose the speed, There are 4 levels of recording speed provided by this instrument as :6.25 mm/s、12.5 mm/s、25 mm/s and 50 mm/s.

b. Press OK button, the parameter area appears red background, then select the filter settings, and press the LEAD button to change the filter state. There are 4 types of filter status provided by this instrument as : 0.05-150Hz、H50 d、H50 d 75Hz、H50 d 35Hz.

c, Press START/STOP button (Starting /Stop button) to start recording. and the symbols of “◀”, “⏸” indicate the acquiring/ recording status respectively . The leading code which is currently recorded will be displayed in the reverse type as the following picture:

**Two standard waveforms recorded Legend:**



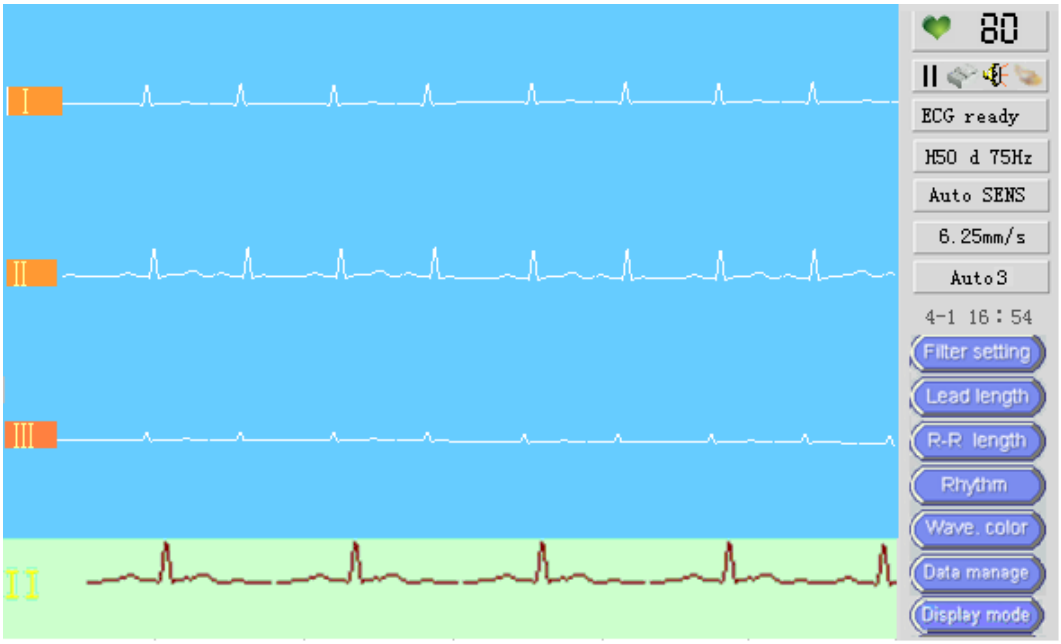

As shown above, the up line is the standard single-channel record mode, the downlink is the rhythm mode, and you can set the rhythm lead in the menu. (see "Parameter setting").

- **Auto3 (Automatic 3 channel)**

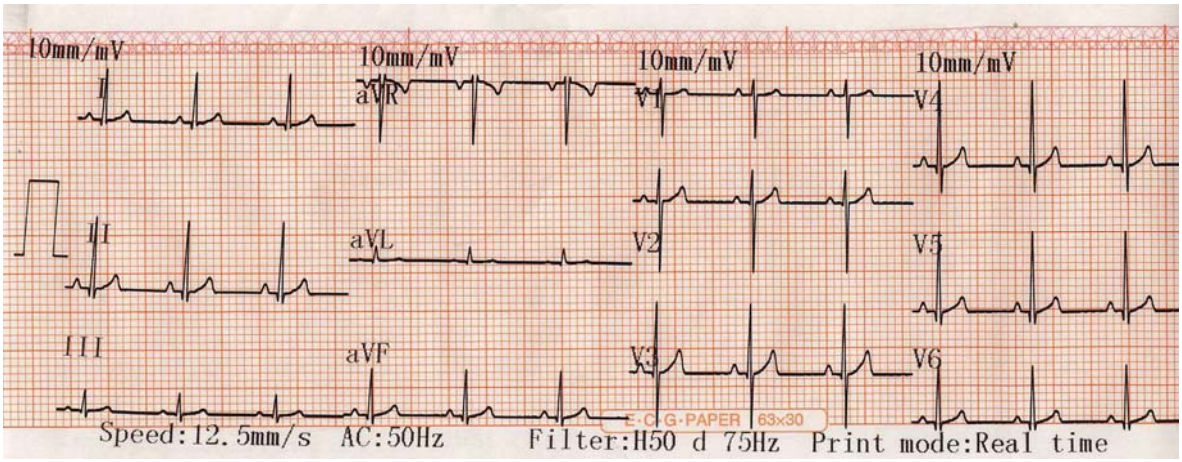
  **When the one-channel unit upgraded to three-channel unit, you can select Automatic 3 mode.**

This mode is the automatic 3 channel, press the

button (Mode switching button) to select (Auto 3), LCD display the working status of machine, as shown below:




**Three standard waveforms recorded Legend:**



**Note:**

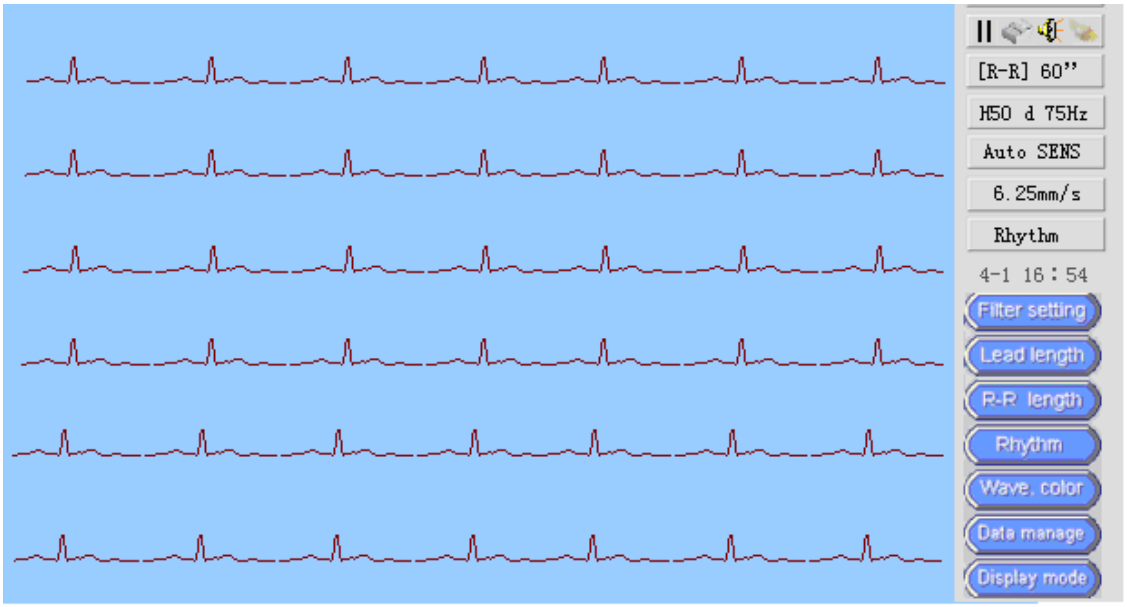
- **Under the automatic recording mode, the leads are unable to be changed through the** **button during recording. The code of lead which is currently recorded will be displayed in the reverse type. You can press the calibration button to print the calibration signal during recording for examining the current sensitivity. However, in this recording mode, the sensitivity is set to "Automatic Gain" and thus unable to be adjusted.**
- **This instrument possesses the function of automatic analysis, however, it just performs the automatic analysis based on the acquired electrocardiogram waveform without considering the total condition of the patient, and there may be some discrepancies between the instrument's automatic analysis result and the physician's diagnosis result. Thus the final conclusion should be made by the physician based on a multi-analysis and diagnosis in combination with the analysis result, clinic symptom of the patient and the other examination result.**

**2) Rhythm mode**

**When the one-channel unit upgraded to three-channel unit, you can select Rhythm mode**

This recording mode is a rhythm lead recording mode. The ECG data of the selected rhythm lead can be acquired by this instrument within 60 seconds ~3 minutes (the duration can be set in the menu). When the waveform acquisition is finished, the system will analyze the acquired rhythm data automatically and can also printout rhythm lead electrocardiogram waveform within a preset duration as well as the rhythm analysis result.

After starting the instrument , you can select the “Rhythm Mode” with the same operating method of recording mode as “ Automatic 3 channel” .Then the instrument will perform data acquisition for the designated rhythm leading. The work status of the whole instrument will be displayed on the LCD screen as the following picture:



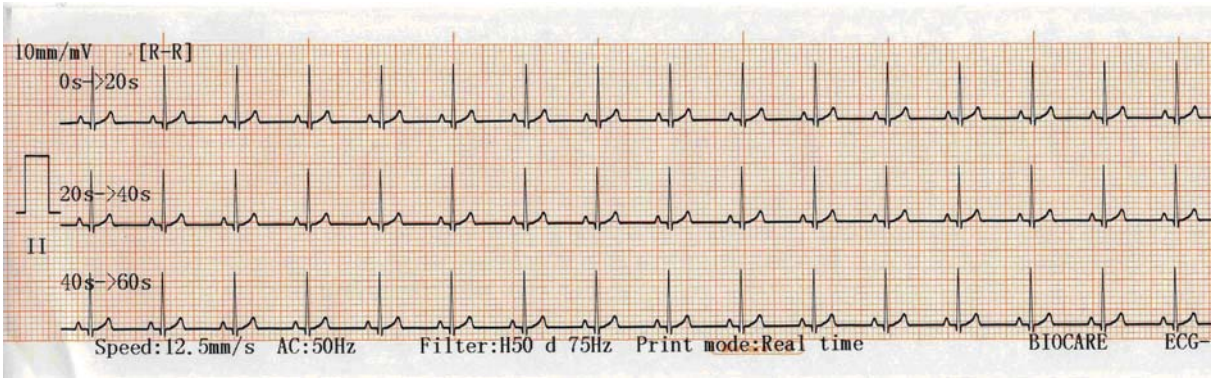

Observe that if the lead ECG waveform is stable in the rough from the displaying of heart rate. If necessary, press the RESET button of “lead shutting off” to stabilizer all the lead waveform instantly.

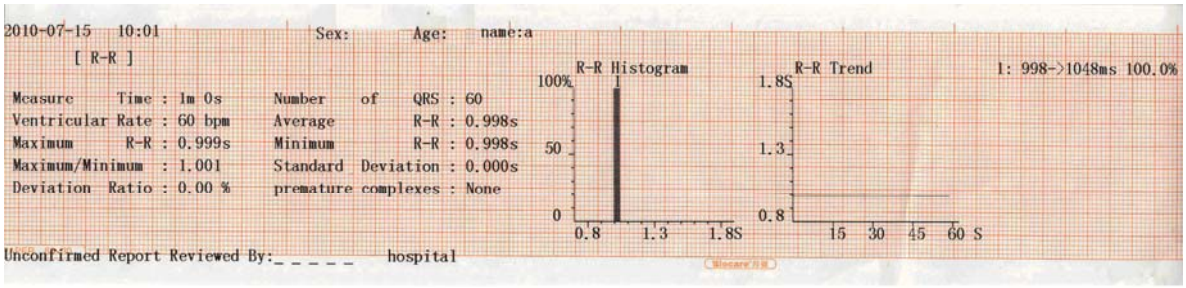
a, Press mm/s CH← button to choose the speed, There are 4 levels of recording speed provided by this instrument as :6.25 mm/s、12.5 mm/s、25 mm/s and 50 mm/s.

b. Press OK button, the parameter area appears red background, then select the filter settings, and press the ◄ ► LEAD button to change the filter state. There are 4 types of filter status provided by this instrument as : 0.05-150Hz、H50 d、H50 d 75Hz、H50 d 35Hz.

c, When the waveform is stable, press START/STOP button ((record / stop record button) to start recording, after recording completely, it will automatically return to the state.

**Long time R-R period record waveform**





2010-07-15 10:01 Sex: Age: name:a
[ R-R ]
Measure Time : 1m 0s Number of QRS : 60
Ventricular Rate : 60 bpm Average R-R : 0.998s
Maximum R-R : 0.999s Minimum R-R : 0.998s
Maximum/Minimum : 1.001 Standard Deviation : 0.000s
Deviation Ratio : 0.00 % premature complexes : None
R-R Histogram
100%
50
0
0.8 1.3 1.8S
R-R Trend
1.8S
1.3
0.8
15 30 45 60 S
1: 998->1048ms 100.0%
Unconfirmed Report Reviewed By:_ _ _ _ _ hospital

**Note:**

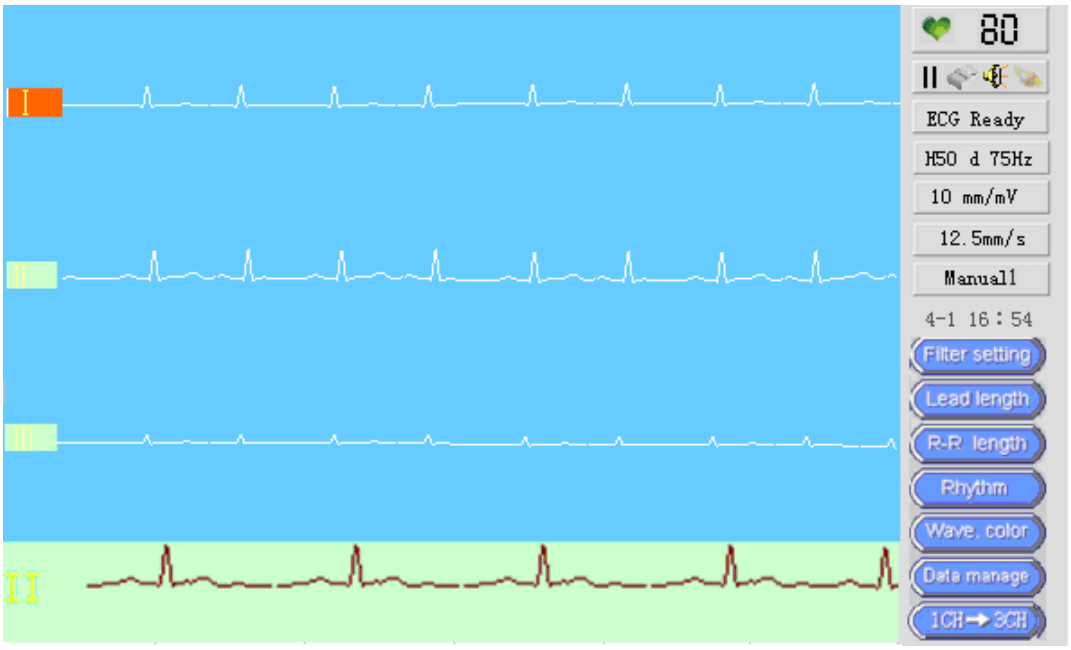
**On this mode, the sensitivity is "Auto SENS" and it can not be adjusted.**

**3) Manual Mode**

This instrument provides manual mode for recording ECG waveform, 1 channel-unit including “Manual 1 channel” and “Manual 2 channel” ; 3 channel-unit including 3 manual recording modes such as “Manual 1 channel”, “Manual 2 channel”, “Manual 3 channel”, Under the manual recording mode, you can switch to the wanted leading or leading group freely. However, under this mode, the instrument is unable to perform analysis to the acquired waveform and output the measurement result as well.

■ **Manual 1 (Manual 1 channel)**

After starting the instrument, you can Press MODE button to select the "Manual 1 channel" with the same operating method of recording mode as "Automatic 1 channel". This mode is the manual mode corresponding to "Automatic 1 channel" mode, and the work status of the whole instrument will be displayed on the LCD screen as the following picture:

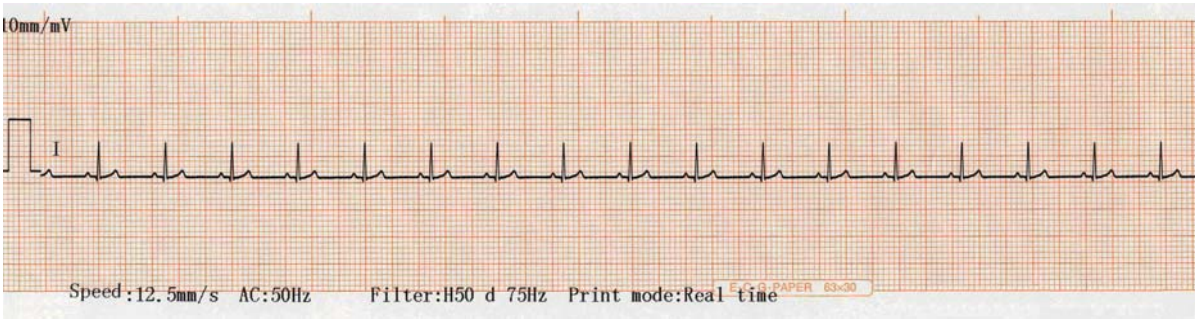



a, Press mm/s button to choose the speed, There are 4 levels of recording speed provided by this instrument as :6.25 mm/s、12.5 mm/s、25 mm/s and 50 mm/s.

b, Press BACK button to choose the sensitivity, there are four levels:: 2.5mm/mv、5 mm/mv、10 mm/mv、20 mm/mv;

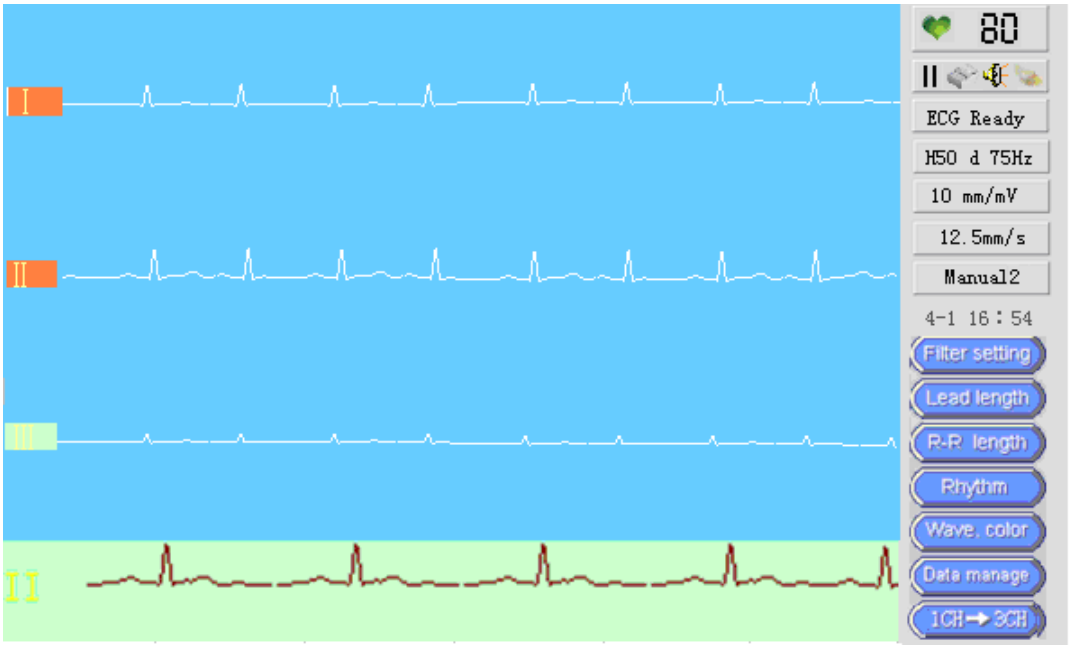
c, When the waveform is stable, press START/STOP button ((record / stop record button) to start recording, during the record process, you can press LEAD button to choose the recorded lead group, the length of time for lead group is controlled by the user, the recording lead code is highlighted , if interrupt or end the recording, please press the START/STOP button (Start/stop record)to return to the recording state.

**ECG Legend of Manual mode**




■ **Manual 2 (Manual 2 channel)**

This mode is the manual recording mode corresponding to the "Automatic 2 channel", and the work status of the whole instrument will be displayed on the LCD screen as the following picture:



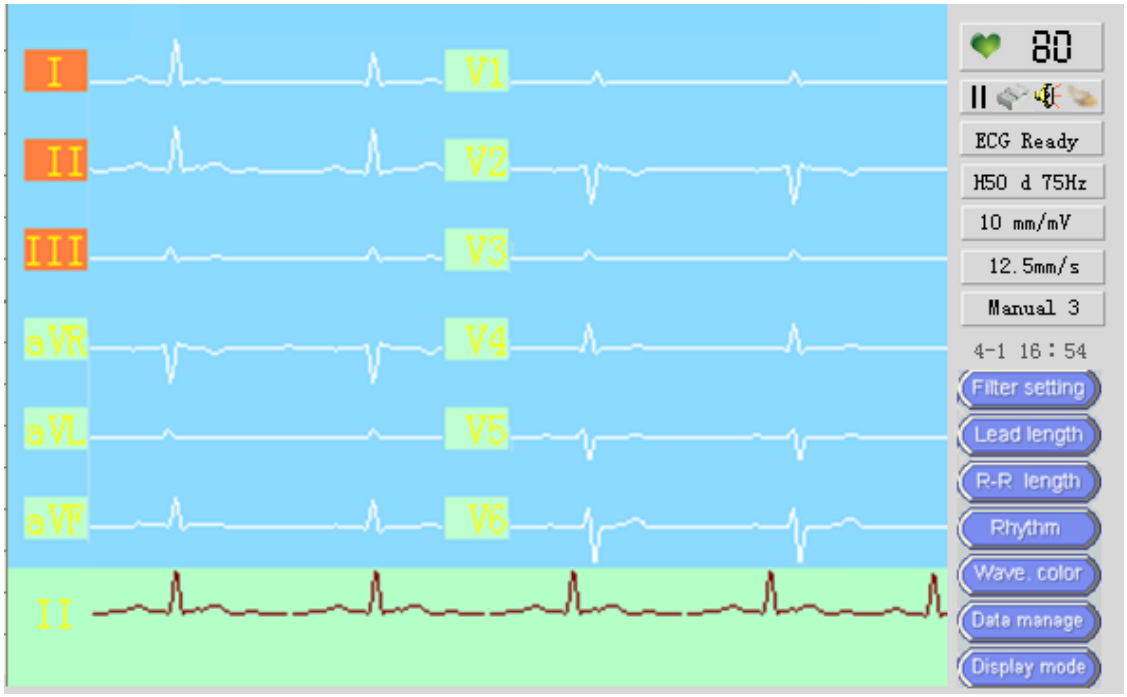

**Note:**

**Please refer to the recording mode of "Manual 3 channel" for the detailed operations and recording**

■ **Manual 3 (Manual 3 channel)**

**When the one-channel unit upgraded to three-channel unit, you can select manual 3 channel mode.**

This mode is the manual recording mode corresponding to the "Automatic 3 channel", and the work status of the whole instrument will be displayed on the LCD screen as the following picture:




**Note:**

**Please refer to the recording mode of "Manual 3 channel" for the detailed operations and recording**

**The lead switch sequence**

Switch to right lead button (LEAD/▫ button) is for switch to the right lead in manual and rhythm modes during recording.

**The lead switch sequence in various recording modes is as follows:**

Automatic 1 channel (Standard 1 channel automatic mode):

Ⅰ→Ⅱ→Ⅲ→aVR→aVL→aVF→V1→V2→V3→V4→V5→V6→Ⅰ→Ⅱ→Ⅲ……

Automatic 2 channel (Standard 2 channel automatic mode):

Ⅰ, Ⅱ→Ⅱ, Ⅱ→Ⅲ, Ⅱ→aVR, Ⅱ→aVL, Ⅱ→aVF, Ⅱ→V1, Ⅱ→V2, Ⅱ→V3, Ⅱ→V4, Ⅱ→V5, Ⅱ→V6, Ⅱ→Ⅰ, Ⅱ……

Automatic 3 channel (Standard 3 channel automatic mode，for 3-channel using):

Ⅰ, Ⅱ, Ⅲ→aVR, aVL, aVF→V1, V2, V3→V4, V5, V6→Ⅰ, Ⅱ, Ⅲ……

Rhythm mode (Rhythm lead analysis mode，Applies in the three channel)

Rhythm leading (Rhythm) can be changed in the menu setting, while it is also can be changed by pressing the

buttons before recording.

Manual 1 channel ( Standard 1 channel manual mode):

Ⅰ→Ⅱ→Ⅲ→aVR→aVL→aVF→V1→V2→V3→V4→V5→V6→Ⅰ→Ⅱ→Ⅲ……

Manual 2 channel ( Standard 2 channel manual mode):

Ⅰ, Ⅱ→Ⅱ, Ⅱ→Ⅲ, Ⅱ→aVR, Ⅱ→aVL, Ⅱ→aVF, Ⅱ→V1, Ⅱ→V2, Ⅱ→V3, Ⅱ→V4, Ⅱ→V5, Ⅱ→V6 , Ⅱ→Ⅰ, Ⅱ……

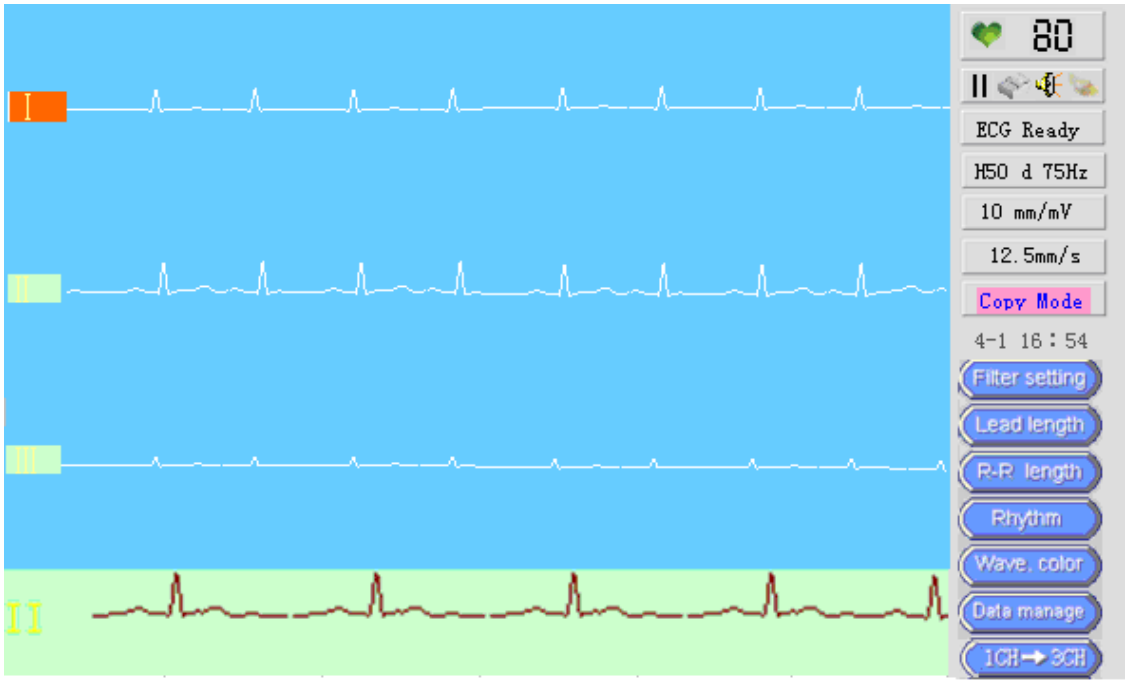
Manual 3 channel (Standard 3 channel manual mode，for 3-channel using):

Ⅰ, Ⅱ, Ⅲ→aVR, aVL, aVF→V1, V2, V3→V4, V5, V6→Ⅰ, Ⅱ, Ⅲ……

Switch to left lead button (
button) is for switch to left lead in manual and rhythm modes during recording, and the lead switch sequence is contrary to the right switch sequence.

## 5.4 Copy of electrocardiogram waveform data

When the electrocardiogram recording is finished, the recorded waveform can be copied by pressing the button by users, and the instrument will copy the ECG data of the previous patient and display it onto the screen automatically. You can press the START/STOP button to trace the previous data, information about the patient and the analysis result. The following screen will be displayed:




**Note:**

- **The electrocardiogram of the previous patient can be copied by pressing the COPY button only when 12-lead ECG waveform and data is analyzed and recorded in the non-manual mode**
- **If the operation of instrument shutting down has been performed after the recording of previous patient, the COPY button will be invalid.**

## 5.5 Matters need attention during ECG waveform measurement and analysis:

**(1) When the myoelectric or the power supply interference is relatively strong, the identification of P wave and Q wave is not always reliable. And the identification of ST section and T wave may not be reliable because of the baseline drift.**

**(2) Sometimes the ending position of S wave and T wave turns to be blended and unclear, and it might introduce the error to the measurement.**

**(3) When the detection of R wave is missed because of the Low voltage of QRS, there might be a large error in the heart rate measurement.**

**(4) The calculation of electrical axis of heart and the demarcation point identification for QRS wave is not always reliable because of the Low voltage of QRS.**

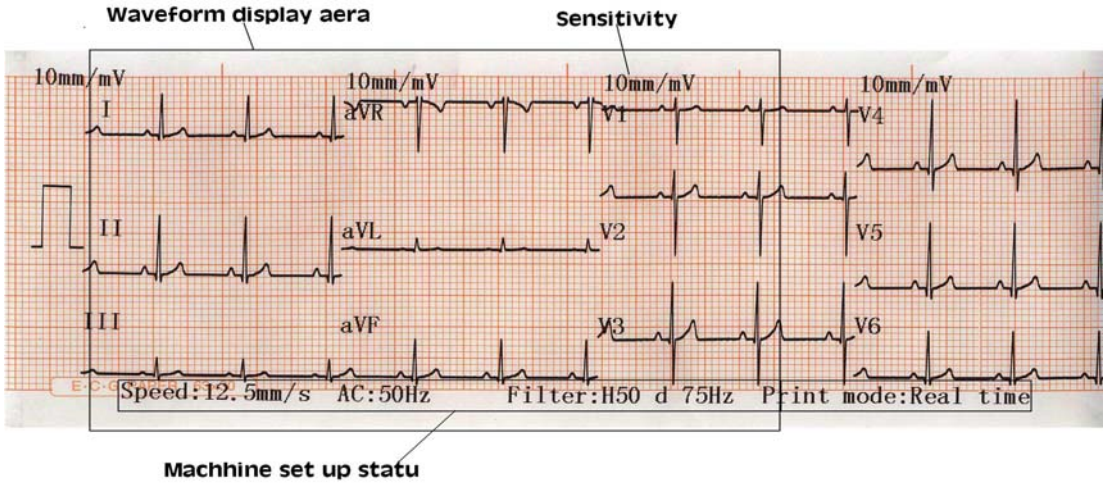
**(5) frequent (repetitive) premature ventricular contraction might be detected as the representative beat occasionally .**

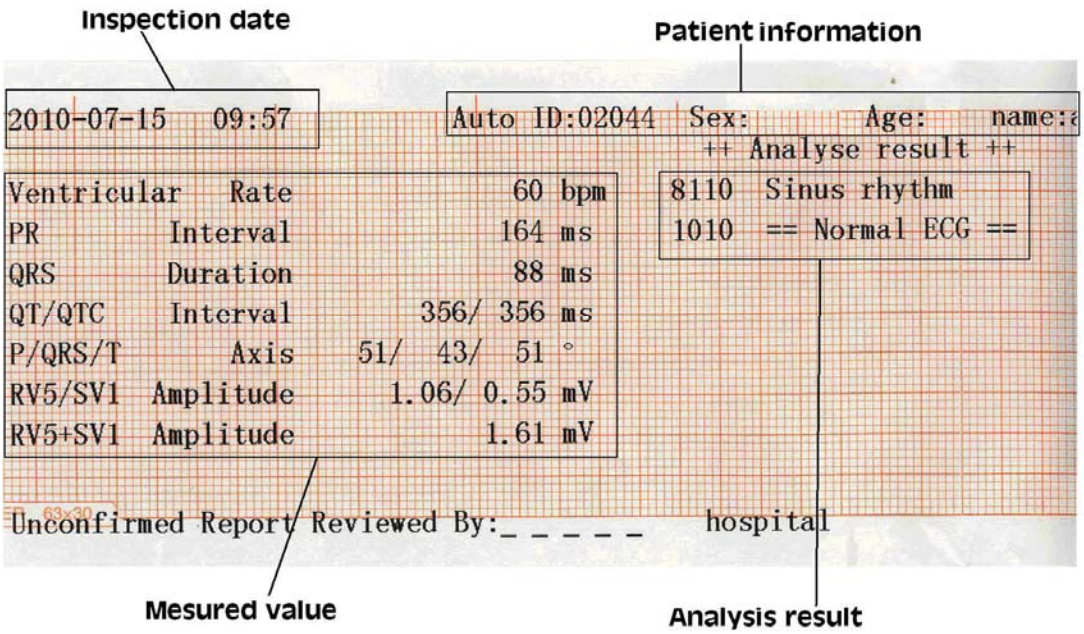
**(6) The P wave may be hard to be identified in presence of multi-arrhythmias thus the related parameters may not be reliable**

## 5.6 Explanation of the ECG Record Sample

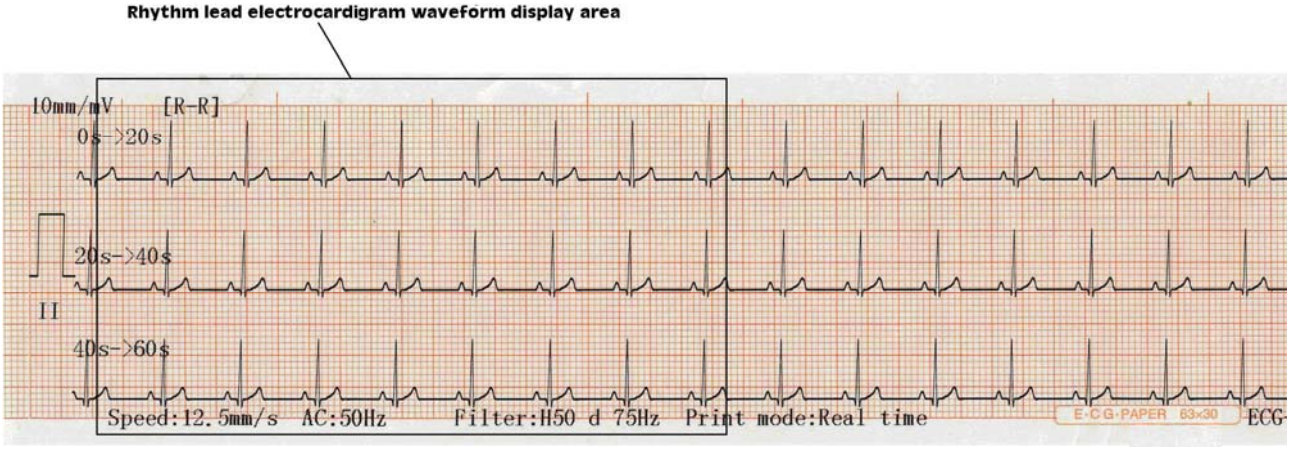
**3-channel**

**Three lines of standard ECG waveforms**




Inspection date
Patient information
2010-07-15 09:57
Auto ID:02044 Sex: Age: name:
++ Analyse result ++
Ventricular Rate 60 bpm
PR Interval 164 ms
QRS Duration 88 ms
QT/QTC Interval 356/ 356 ms
P/QRS/T Axis 51/ 43/ 51 °
RV5/SV1 Amplitude 1.06/ 0.55 mV
RV5+SV1 Amplitude 1.61 mV
8110 Sinus rhythm
1010 == Normal ECG ==
Unconfirmed Report Reviewed By:_ _ _ _ _ hospital
Mesured value
Analysis result

**Long time R-R period record waveform**

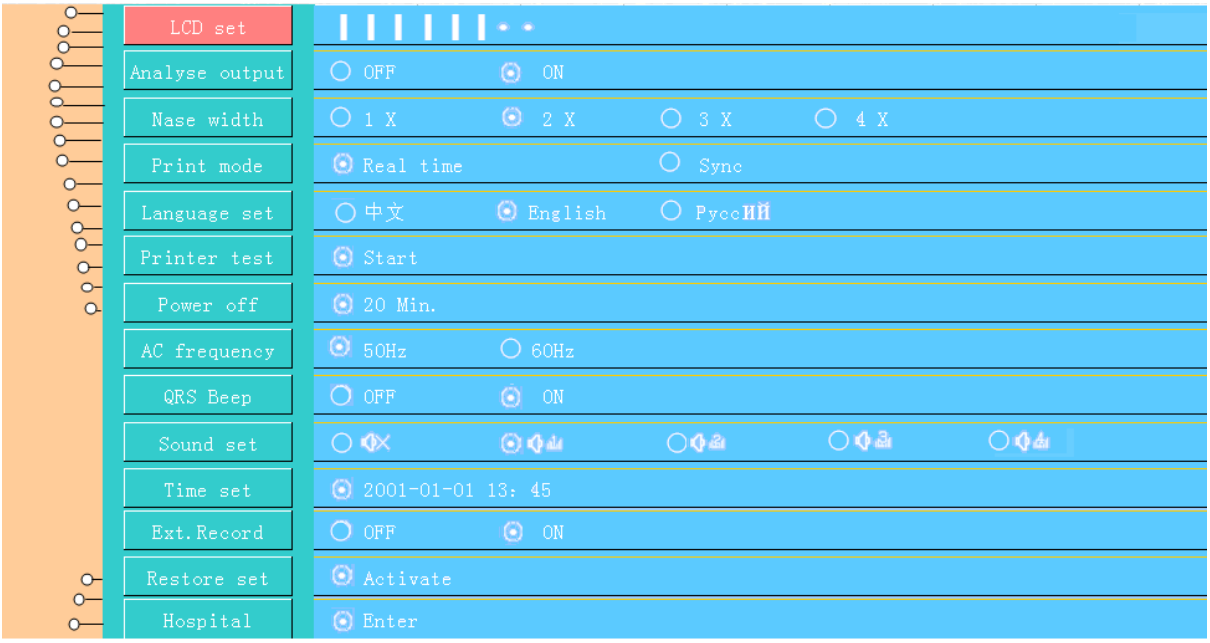


# Chapter 6 System Parameters Setting

The system parameters of this instrument can be set in the menu.. The displayed parameters in the menu are the factory default value, and the users can set the parameters which need to be changed before electrocardiogram recording.

## 6.1 Main menu

After starting the instrument , press the button to enter into the Menu setting interface, users can press LEAD button to move the Move the selection box to each option as shown below:




In the Menu setting interface, the pink background is the current selected sub-menu, press OK button to enter the lower menu, press MODE RESET button to move the selection box for the other option.

## Parameters list：

| Parameters | Setting Value | Defaulting Value | Comment |
|---|---|---|---|
| LCD set | | | Adjust the LCD contrast |
| Analyse output | OFF，ON | ON | Automatic analysis of report output options |
| Base width | 1x、2x、3x、4x | 2x | Select the width of the waveform baseline |
| Print mode | Real time，sync | Real time | Select data collection print mode |
| Language set | 中文 English Русский | English | Setting the display language |
| Printer test | Start | Start | Print a test triangle |
| Power off | 0 Min、5 Min、10 Min 60 Min | 20 minutes | Set Auto shutdown time |
| AC frequency | 50Hz、60Hz | 50Hz | Network Power Frequency Selection |
| QRS Beep | OFF，ON | OFF | Select Heart Rate Detection tone switch |
| Sound set | | | Select voice tone and switch |
| Time set | XXXX-XX-XX XX: XX | The current time | Year - month - day hour: minute format input |
| Ext. Record | OFF，ON | OFF | Select the external input signal record |
| Restore set | Activate | Activate | Restore the state of factory setting |
| Hospital | Enter | Enter | Input hospital name information |

- **LCD set**

  Move the selection box to “LCD set”，press

button and then press

button ， users can adjust the LCD contrast.

- **Print mode**

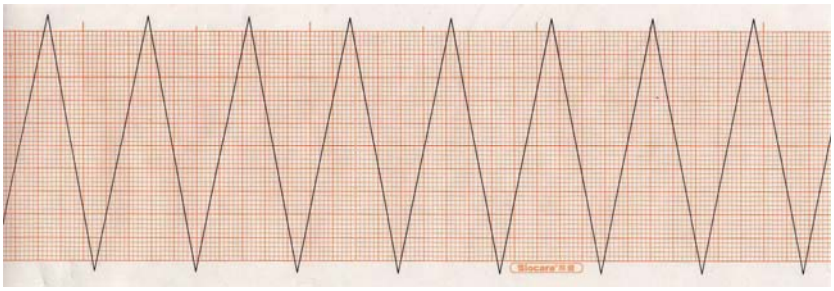
  Real-time print mode is based on changes in the human body in real time as a ECG recording of printing method; The synchronization is the standard twelve lead ECG data is synchronized, it means that each lead waveform situation at the same period of time . Data for each lead is the same starting time. Users can easily observe the data of each lead at the same time period.

**Note**:

**Synchronous printing mode is only effective in the automatic mode.**

- **Printer test**

Move the selection box to "Printer set", Press OK button , then the instrument can print the triangle wave as shown below, Users can observe the triangular wave whether there is a breakpoint, bending or wave phenomena, and then test the print head is in good condition or not.

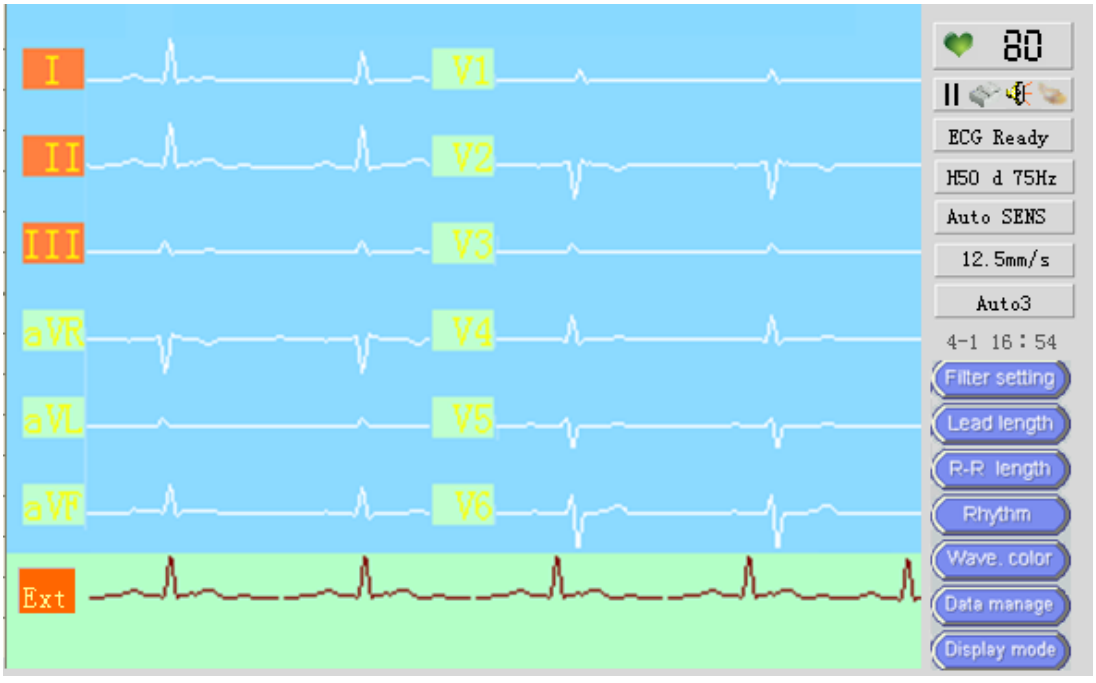


- **AC frequency**

This setting needs to match the frequency and use the AC, if you set it improper; it will affect the mapping results and analysis.

- **External Record**

External input is set as "On ", the machine enter into an external input screen, the screen display as shown below:



Press START/STOP button（Start/Stop record button）to print the external input waveform.

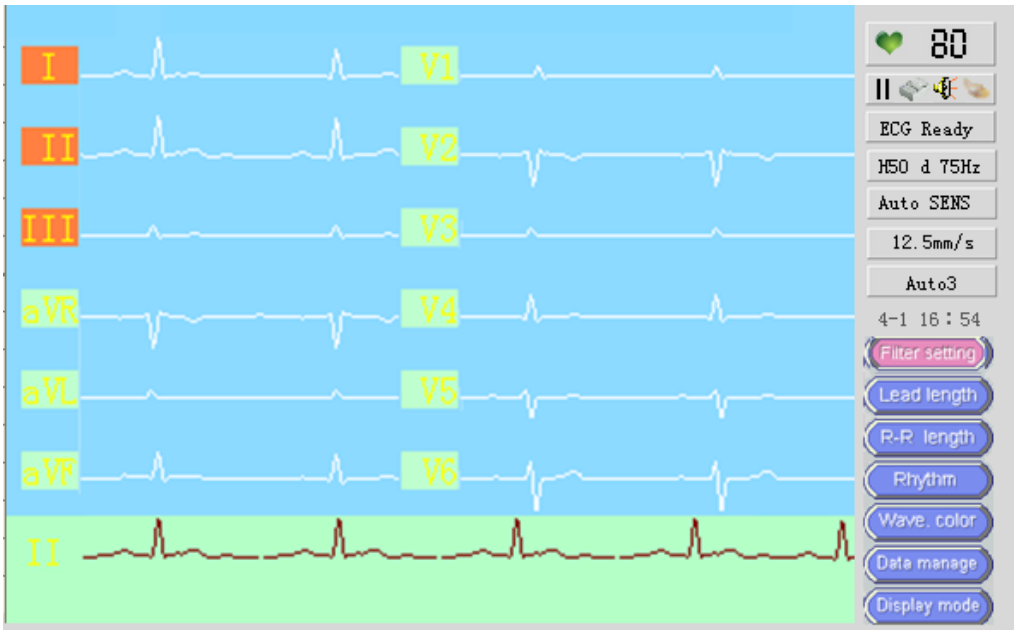
■ **Hospital information**

Move the selection box to “Hospital”, press OK button to enter the hospital edit interface:

Users can select the CH and EN to input, detailed operation please see Chpter7 “ Name inputting”。

## 6.2 Parameter setting

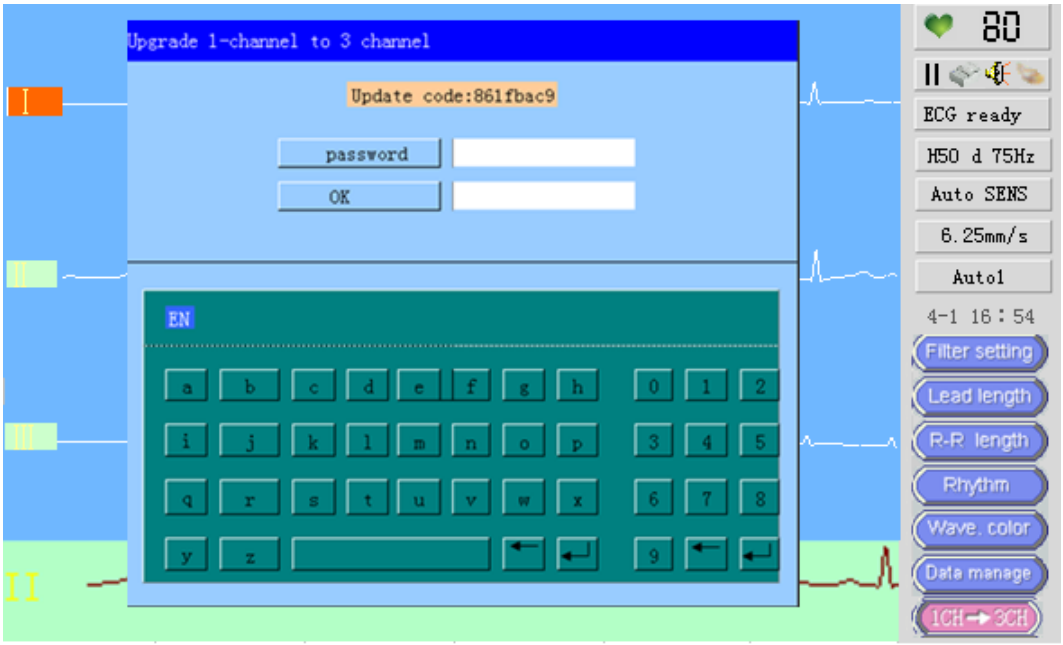
In the main interface, press the OK button , and then press MODE RESET button, users can move the selection box to set each parameter, as shown below:



| Parameters | Setting Value | Defaulting Value | Comment |
|---|---|---|---|
| Filter setting | 0.5-150Hz, H50 d, H50 d 75Hz, H50 d 35Hz | H50 d 75Hz, | Filter setting |
| Lead length | 3s—12s | 3s | The length of a single channel recording time |
| R-R length | 30s—180s | 60s | Selection R-R duration lead length |
| Rhythm | Ⅰ, Ⅱ, Ⅲ.....V4,V5,V6 | Ⅱ | Select the rhythm lead |
| Wave.color | White, black, red, green, blue, yellow, pink, blue, orange, purple | white | Select the display color of lead |
| 1CH ➔3CH | / | / | According to the need to upgrade single-channel to three channel |
| Display mode | 3, 6, 12 | 12 | Select the display mode of lead |

■ **Upgrade 1-channel to 3 channel**

In the main interface, press the OK button, and then press MODE RESET button to select 1CH ➔3CH as shown below




Enter the upgrade password, the system prompts: upgrade successful, please reboot.

**Note:**

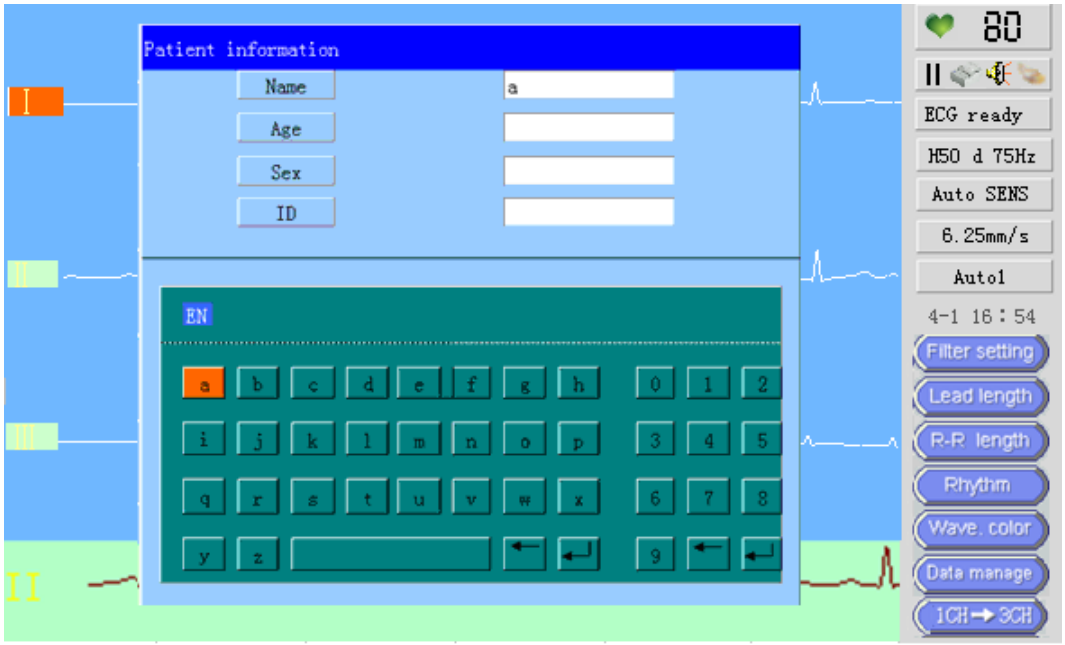
**After the upgrade, the user can not return to the 1-channel unit, please pay attention when you want to upgrade!**

# Chapter 7 Patient Information and Data Administration

This chapter introduces how to input and display the patient information, as well as operation procedures of storing and transmitting of ECG data.

## 7.1 Patient Information Inputting

In the main interface, press 1mV ID button, the patient information interface pops-up, after setting it , press button to return to the main interface.



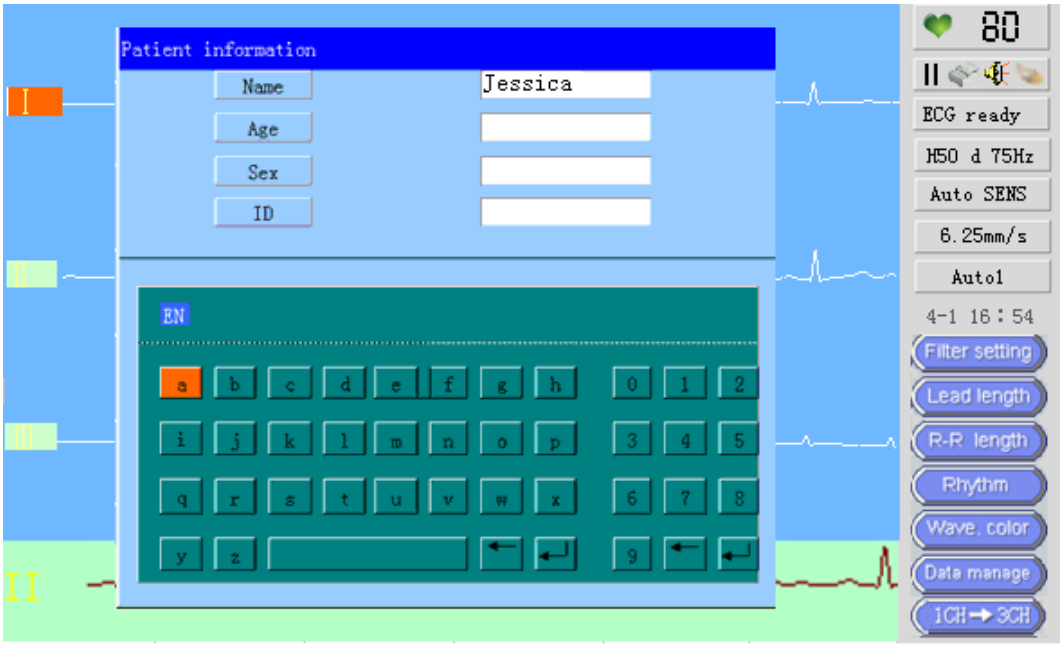

The screen displays the patient name, age, gender and ID number four setting items, users can input the information according to the actual situation of the patient.

## ■ Name inputting

Moving the selection box to select "Name", and then press the OK button or the MODE RESET button to move the selection box to the "EN" or "CH", users can press the LEAD button again to switch the input mode.

### Letters input

Select the input mode "EN", in the letter keyboard enter the corresponding letter, and press the OK button to return to achieve the information inputting.




## ■ Age inputting

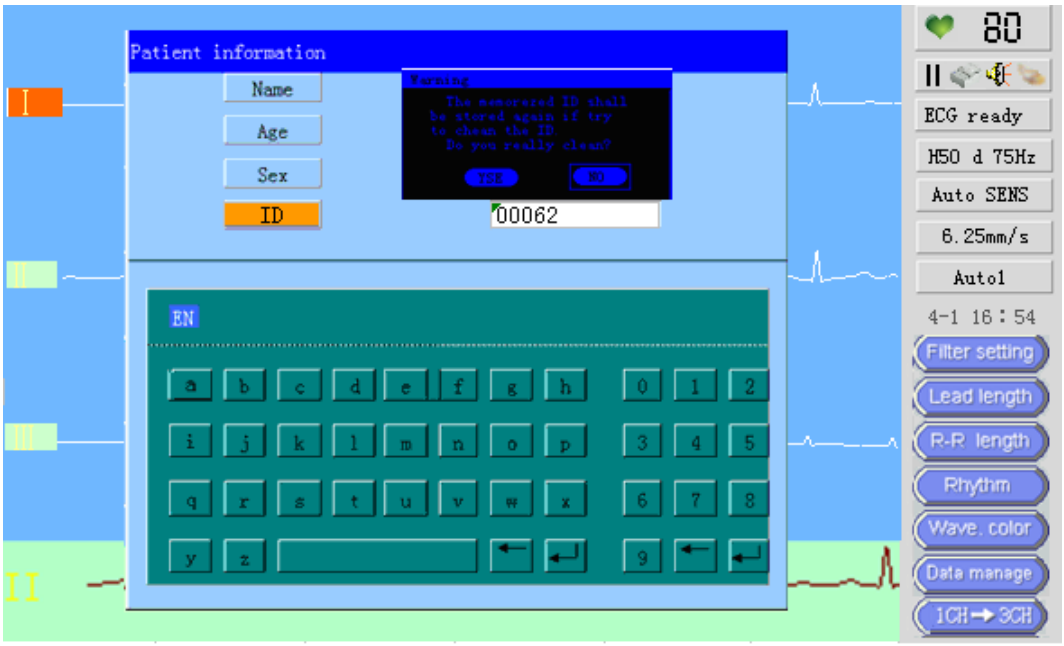
when users is inputting the Age , the system will automatically to stay the selection box in the numeric keypad, in the numeric keypad, users can move the selection box to select the desired number of input, and then press OK button to input the information.

## ■ Sex selection

The default is "None", "None" means that in the report the gender column is blank, it is filled by the doctor, press the LEAD button to select "Male", "Female" or "None ", and then press BACK button to return.

■ **ID**

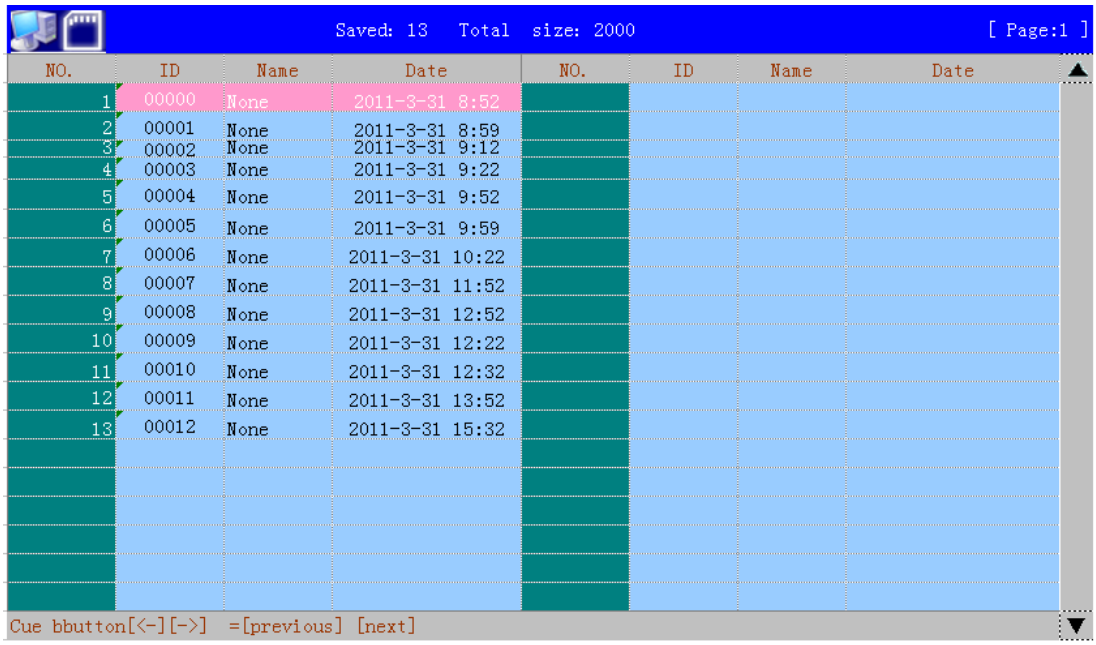
The machine automatically to give a unique ID number for collected ECG data ,and named the ID number to store ECG data; in this option, press the OK button, the instrument will prompt weather to clear ID(as shown below). Because the storing is named by the ID number, if you choose "YES", it will result in duplication of storage, at last resulting in data management confusion.



## 7.2 Data Manage

This instrument provides the storage medium internal memory for storing ECG ,Analysis and measurement recording ECG data can be stored in the storage medium.

In the main interface, press OK button ,then press MODE RESET button to move the selection box to “Data manage”, after selecting, press OK, the input interface will display: :

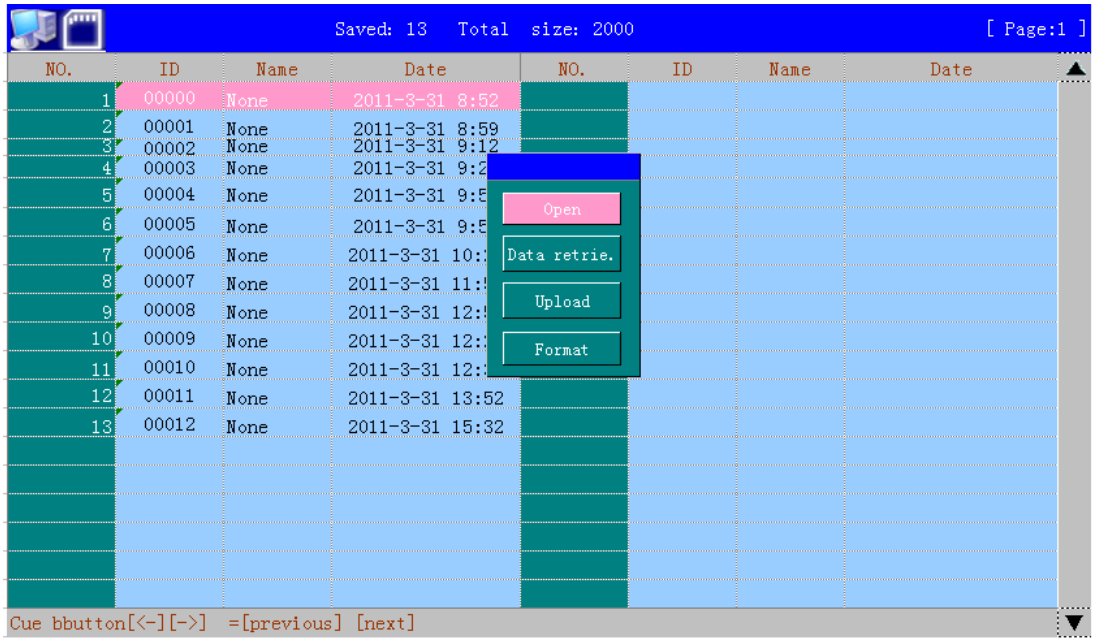



When the instrument complete an ECG recording, ECG analysis results, and patient electrocardiogram data constitute a file saved in the default storage medium for Data query and management in the future.

- **Internal Memory**

The instrument’s internal memory can store up to about 2,000 copies of ECG data (the actual situation according to the liquid crystal display). When the data storage is full, the new ECG data will automatically replace the first ECG data.

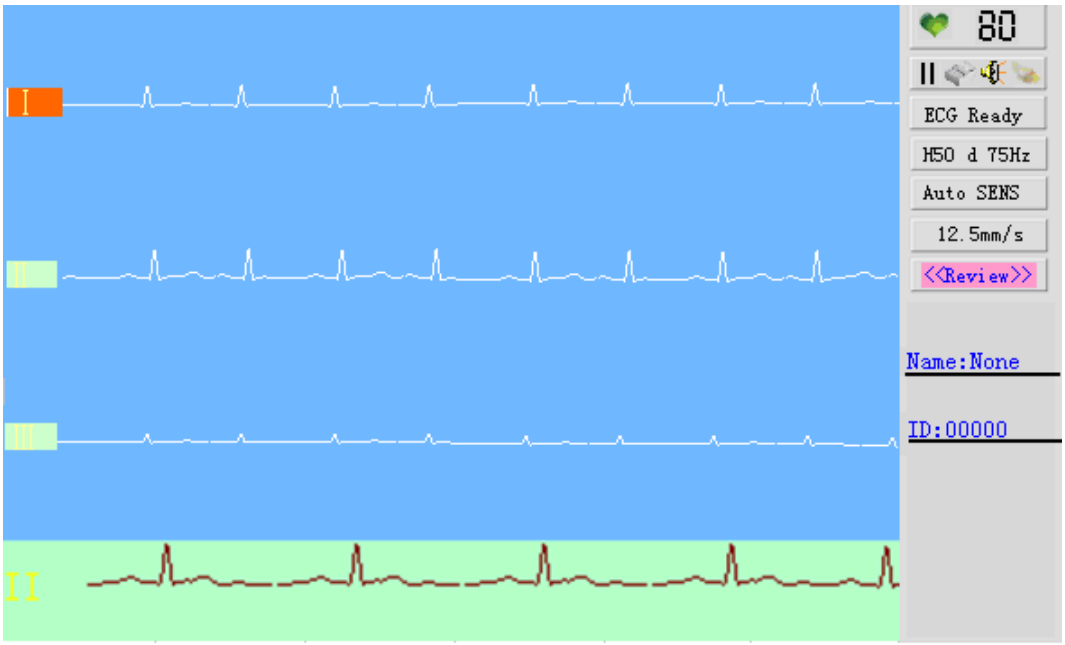
The current state of storage media is displaying on the screen, Store file and the patient's ID number in sequence to be storied, users can query and playback the waveform.
In the data storage screen, move the selection box to select the inspection ECG data, and then press the OK button to pop-up such dialog box as shown below:




There are four options for user using: "open", "Data retrieval", "upload" and "Format", users can carry out the necessary processing and operations for ECG data.

- **Open file**

Select "Open" option to playback the waveform and data access, LCD display the following "data playback" picture:

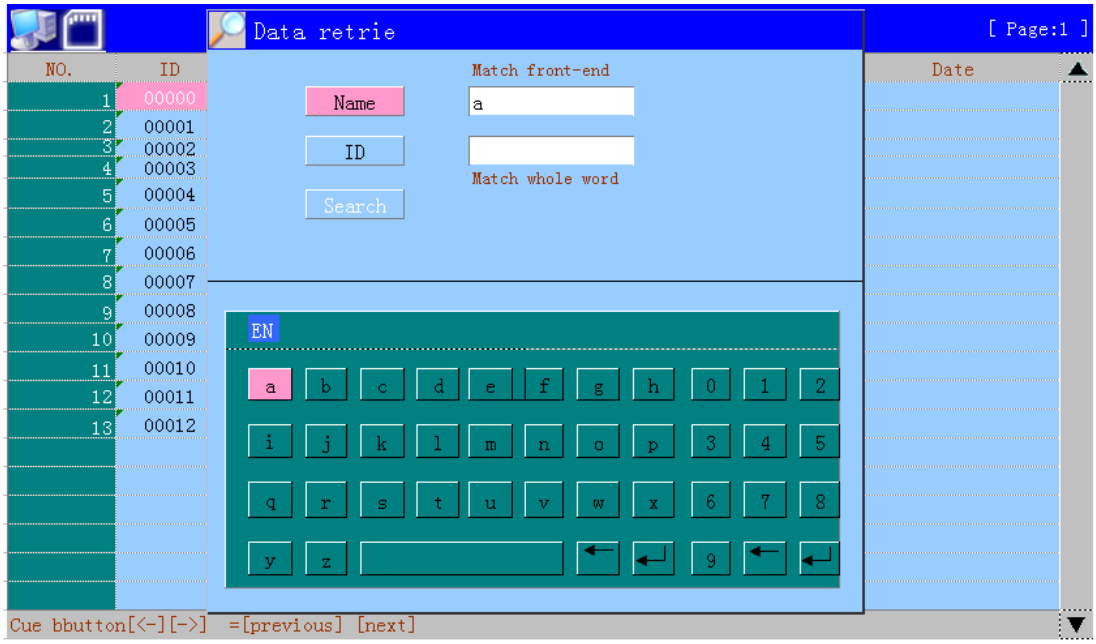



This picture include 12-channel ECG waveform, the patient name, ID number , select the paper speed and press the button to print this ECG data.

Print ECG data in the "Wave Playback" mode, the instrument will automatically to print it as "Auto 3" mode, after printing the waveform, it will automatically to print the stored analysis results and the patient name ,ID and time.

## ■ Data retrieval

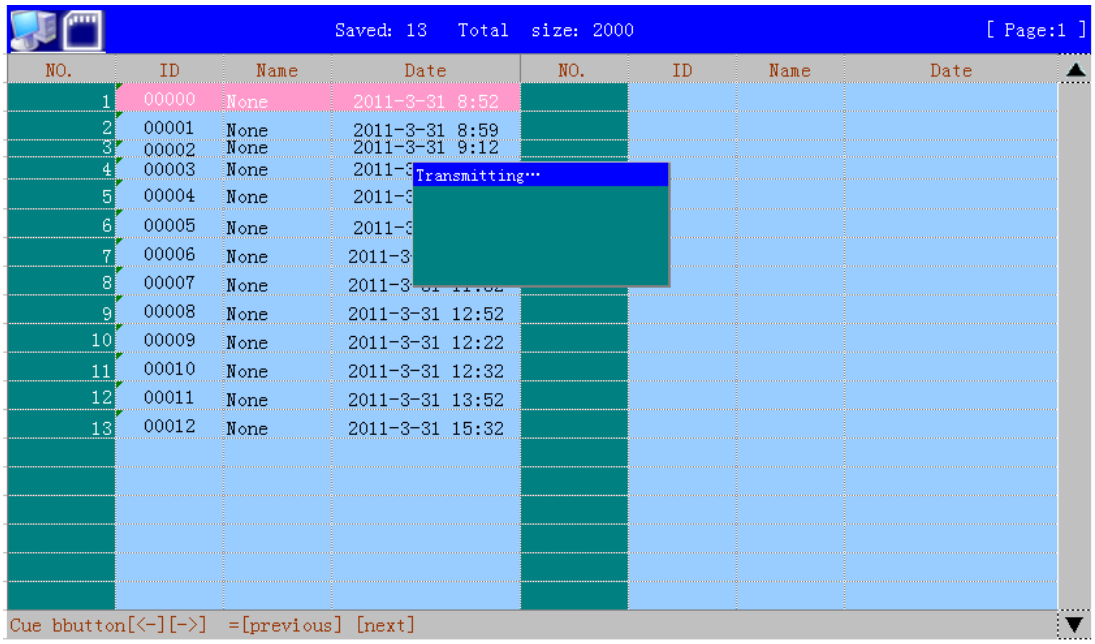
Select ”Data retrieval” option, and press OK button:

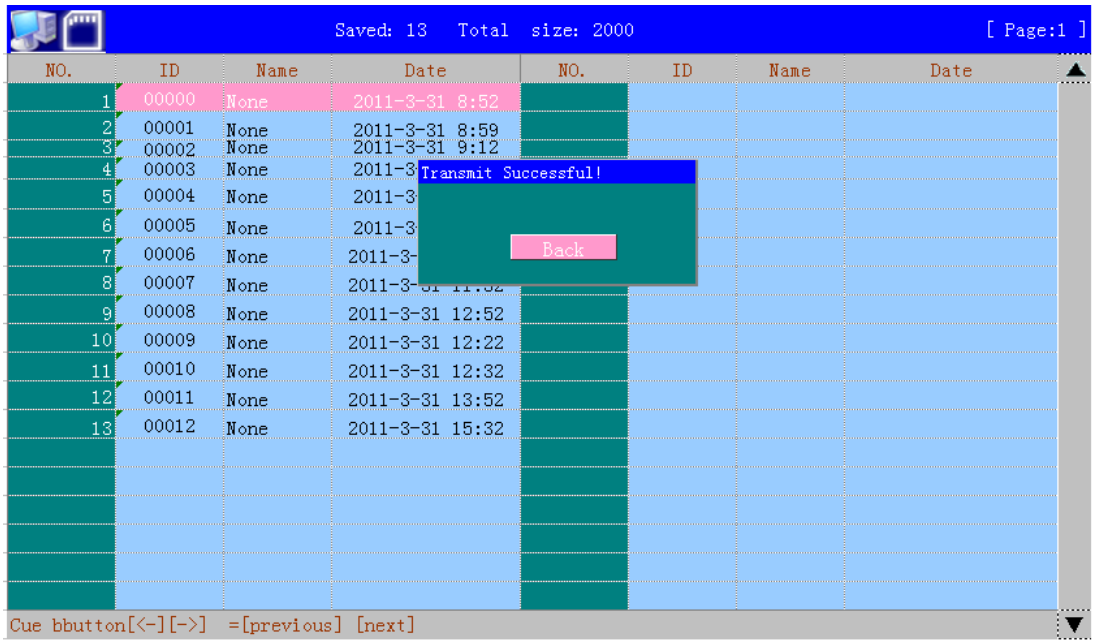



There is "Name" and "ID" option in this dialog, in this dialog, users can retrieve the required ECG data.

## ■ Upload file

Select ”Upload” option， and press OK button：



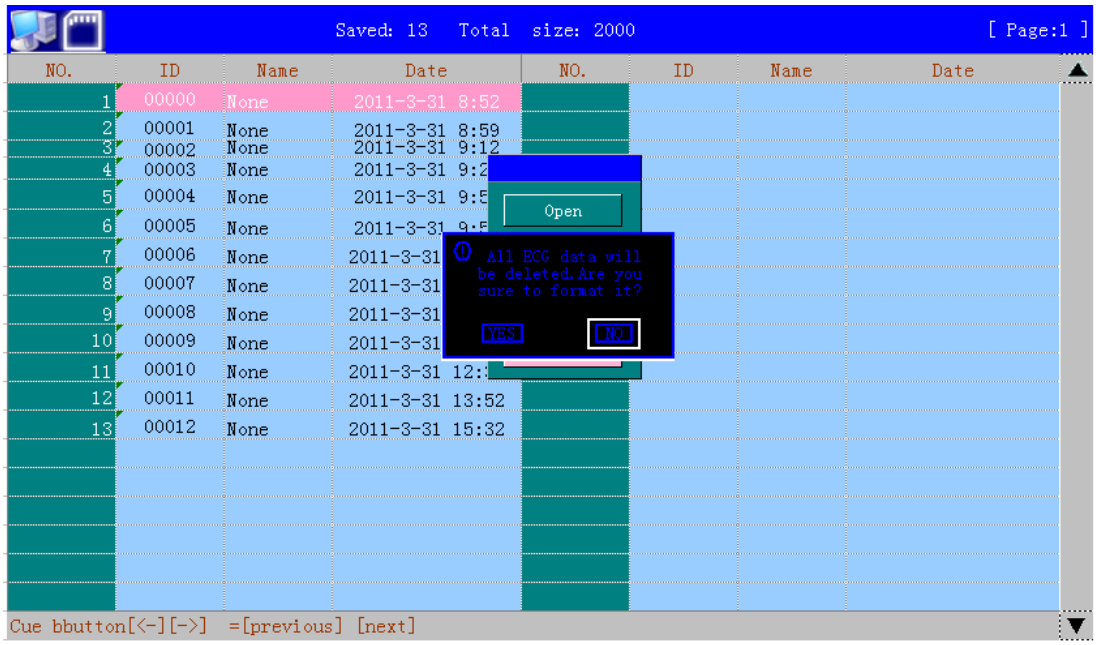




**Note:**

**The data transfer function must be related to the user has the hardware, software support, Specifically refer to the instructions in this section," Management of Communication between the Product and Computer**

## ■ Format

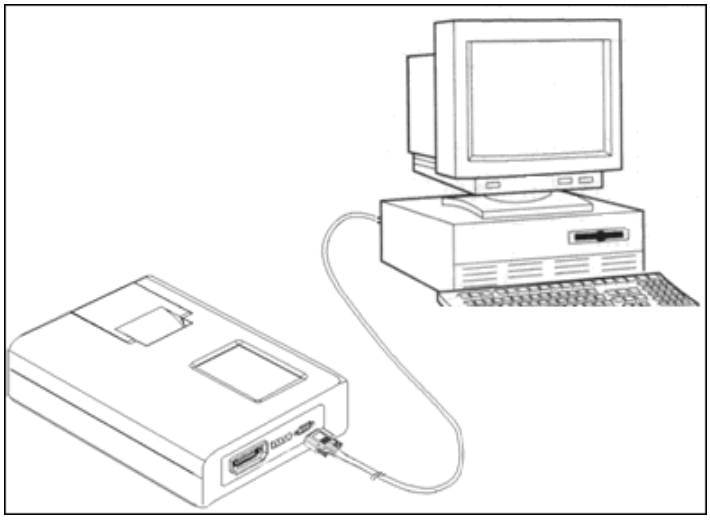
Select ”Format” option, and press OK button:




The system prompts weather to format the memory, If format memory, the memory of all the corresponding records will be deleted, and can not be restored, please be sure!

## 7.3 Management of Communication between the Product and Computer

The product can conduct data transmission to computer through RS232 port. Before using this function, make sure that the product has beend reliably connected to the computer through RS232 cable, and that the ECG management software designed by the computer has been installed in the computer. The connection between the product and the computer is as follows:



When the product is connected to the computer, select " Transmission" in the function menu of the product function and press OK button to realize data transmission.

**Note:**

**1、RS232 connection cable should be the cable provided by the company along with the ECG management software or with the same specifications as it.**

**2、For detailed functions and operations of the ECG management software, please refer to the manual of ECG management software.**

**3、The ECG management software is an optional product, which can be purchases by contacting business personnel of the computer in case of need.**

# Chapter 8 Servicing and Maintenance

## 8.1 Matters needing attention about the repair and daily maintenance of the product

a. There is no part inside of the product that requires the user to conduct maintenance, the user's maintenance work normally involves the appearance cleaning of the product and checking of the effectiveness of controlling buttons and integrity of the outer insulating protection of the leads, thus the user should not dismantle the machine without approval;
b. When abnormal conditions of the product appear, mark the part with problem and conduct repair immediately, and do not use products with malfunctions. As there may be high voltage inside of the product that would be harmful to human, the repair of the product must be conducted by specialists with qualification, no other person shall open the body case of the product to conduct repair. The technical materials such as electrical schematic diagram and parts list that are needed for the repair of the product can only be provided to the repairing personnel with qualification;
c. Repair of product must be conducted according to the original design, and no model alteration is allowed. After repair, the product must go through necessary safety examination and measurements before it can be used;
d. The product and all its accessories must be maintained regularly, with a time interval no longer than half a year.
e. The product is the force measuring instruments, users should statutory qualifications to the local institutions to apply the measurement test, test period is not less than one year.

## 8.2 Maintenance and Replacement of the Built-in Battery

The built-in battery of the product is rechargeable battery which is installed inside of the product. As the service life of rechargeable battery is related to the times of charging and discharging, it is recommended to use AC power supply when the conditions permit to prolong the service life of the rechargeable battery. The electric capacity of the built-in rechargeable battery is displayed on the monitor of the product when using the battery to work, so the user can know whether the battery needs recharge through observing the electric capacity of the battery. When the battery is fully charged but the working time is less than 30 minutes, or the battery cannot be recharged, the built-in battery may have lost its effectiveness and should be replaced. As the body case of the product should be dismantled to replace the built-in battery, the replacement of the built-in battery should be conducted

by professional maintenance personnel, and the user should not replace it on himself/herself in order to avoid electric shock. Meanwhile, the rechargeable battery with the same specifications must be used to replace the built-in battery to prevent accidents from happening. The detailed steps to charge the battery, display the electric capacity and protect the battery are explained as follows:

### 8.8.1 Recharging the Battery

There are battery charging and protecting circuits designed inside of the product. When the AC power cord is connected, the battery can be charged. When the product is not use for a long time, at least charge and discharge the battery every three months. When charging the battery, turn the product into standby status, and open the power switch at the back the product. During charging process, the charging indicator lamp on the front face of the product will blink, and when the charging is completed the indicator lamp will illuminate constantly.

### 8.8.2 Capacity Display of the Battery

When using battery to supply electricity, there would be a icon that represents the capacity of the battery in the monitor after the machine is turned on, as shown in the figure below. There are four shapes of the icon which indicate different capacities which are explained below:

: Battery capacity is full;

: Battery capacity is sufficient;

: Battery capacity is not sufficient, needs recharge;

: Battery capacity is empty, needs immediate recharge;

## 8.3 Recording paper

For ensuring the quality of the ECG waveform tracing, the high speed heat sensitive recording paper designated or provided by our company should be used. Using the undesignated recording paper may cause problems such as the service life of heat sensitive printing head falling , the unclear waveform recording and paper jam and should be given particular attention.

(1) Do not use the recording paper coated with wax , and the paper in the color of ray or black, or else the wax may adhere to heater of the printing head and lead to the printing head failure or damage.

(2) High temperature, moisture and sunlight will cause the color change of the recording paper, thus keep it in the dry and cool environment .

(3) Do not place the recording paper under the fluorescent light for long term or else the recording quality may be affected.

(4) Do not place the recording paper with the PVC plastic material or else it may cause the color change of the recording paper.

(5) When the recording paper is placed in cascade, the recorded waveform may be printed from one piece to another one each other.

(6) Particular attention should be given to the size of the recording paper. The recording paper of which size is not in compliance with the requirement may cause the damage of the heat sensitive printing head or the silicon rubber roll.

## 8.4 Instrument maintenance after using

The following maters should be given particular attention after using the ECG instrument:

(1) Press the ON/OFF button on the control panel to set the instrument in the stand-by status.

(2) Hold the plug to pull off the power supply cable and the lead lines instead of holding the cable.

(3) Clean up the instrument and accessories, then place the dust cover on it.

(4) Keep the instrument in the dry and cool environment. Prevent it from intense shock when moving it.

(5) Do not soak this instrument into the detergent when cleaning it. Please cut off the power supply first when cleaning the outer shell of the instrument . Please clean the instrument with the neutral detergent instead of using the detergent containing alcohol or using the sterilizer.

## 8.5 Inspection and maintenance of lead lines and electrodes

1 The continuity condition can be tested by the multimeter. Please inspect the contacting condition of each lead line based on the following table . The electric resistance between the electrode end and the lead plug pin for each lead line should be less than 10Ω. Please inspect the continuity condition of the lead lines regularly, since the damage of any one line among them will cause the false waveform of corresponding lead or the entire lead in the electrocardiogram. The lead lines can be cleaned with the water and soap as well as sterilized with 75% alcohol ( do not soak the lead lines into the liquid for sterilization).

**Note: The electric resistance of the lead line with the protective function of anti-defibrillation is 10KΩ approximately.**

| **Symbol for connector plug** | R | L | F | RF | C1 | C2 | C3 | C4 | C5 | C6 |
|---|---|---|---|---|---|---|---|---|---|---|
| **Position for plug and pin** | 9 | 10 | 11 | 14 | 12 | 1 | 2 | 3 | 4 | 5 |

2. Bending the lead line in the sharp angle or knotting will decrease the service life of the lead line, thus please perform the electrodes connection after tidying the lead line as possible .
3. The electrodes should be stored well. After using for long term, the oxidation color change of the electrodes may occur due to corrosion and so on , and the electrocardiogram may be affected. If this happens, please replace the electrodes in time.

## 8.6 Maintenance of silicon rubber roll

The silicon rubber roll should be kept in a stable, smooth and clean condition , or else the quality of the ECG recording may be affected . To clean off the stain on the silicon rubber roll, please wipe it along the long axis by a clean soft muslin with a little alcohol, while turning the silicon rubber roll along the transmission direction of recording paper to clean it entirely.

## 8.7 Cleaning of the heat sensitive printing head

The definition of the recorded waveform will be affected by the stain and dust on the surface of heat sensitive printing head. To clean the surface of the printing head , you can open the paper compartment cover after shutting down the instrument , then wipe the surface of printing head gently by the clean and soft muslin with a little alcohol . The residual contaminant on the printing head should be wetted with a little alcohol before removing with the soft muslin. Do not scrap the surface of printing head with the hard article or else the printing head will be damaged. Do not close the paper compartment cover before the alcohol is evaporated entirely .The printing head should be cleaned once per month when normally used.

## 8.8 Fuse replacement

If the AC power indicator light does not light when the AC power cable is connected and the power switch at the back of the instrument is on , as well as the instrument is unable to be started by pressing the ON button on the control panel or the battery status symbol as is displayed after starting the instrument. If the AC power supply at the socket is confirmed to be in a normal condition, it is probable that the fuse has blown. At this time the AC power supply fuse should be replaced . The fuse is located in the internal portion of the instrument and should be replaced by the professional or the manufacturer.

a. Cut off the AC power supply of the product;
b. Turn the product up side down and insert a screwdriver into the tube fuse seat at the bottom of the product and turn the screwdriver until it is separate from the product;
c. Take out the tube fuse in the tube fuse seat to check whether the fuse is melted down, if so, replace a tube fuse with the same specifications, otherwise check the other tube fuse;
d. Install the new tube fuse into the fuse cap and align it to the position of the original tube fuse seat and use a screwdriver to fasten it clockwise;
e. If the two tube fuses are not damaged after inspection, but the product cannot work with AC power supply, then the internal circuit may have malfunction, and the product should be sent to repairing organization with qualification to be repaired;
f. When a new tube fuse is replaced and it is melted down when connecting power supply, then there may be other potential troubles in the internal circuit of the product, and the product should be sent to repairing organization with qualification to be repaired.

# Chapter 9. Common Malfunctions and Eliminating Methods

9.1 Phenomenon of malfunction: waveforms of some leads cannot be detected during waveform recording.

Solution: There are several reasons for this phenomenon as follows:

1）When the product is connected to the patient, the internal baseline stabilization system needs time to adjust, just wait for a while.

2）When the phenomenon occurs when all the leads are in good status of contact, just press the lead closing button to quickly stabilize the waveforms of the channels.

3）There may be breakage of the leads, check the leads.

4）When the above reasons do not exist and this phenomenon still occurs, there may be malfunction in the signal channel of the product, please contact the after-sales personnel of the company or designated maintenance organization.

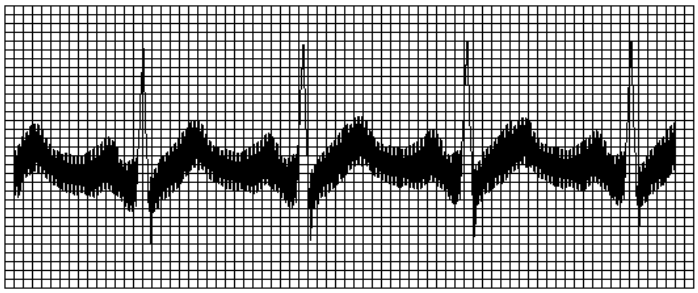
9.2 Phenomenon of malfunction: the waveform information printed has breaking points in the vertical direction

Solution: normally it is because the surface of printing head is contaminated with dusts or dirt, and it can be solved by cleaning the printing head after turning off the machine. If the phenomenon still exist when the printing head is cleaned, then part of the heating units may be damaged and need replacement. Please contact the after-sales personnel of the company or designated maintenance organization to replace the printing head.

9.3 Phenomenon of malfunction: some buttons or all the buttons on the control panel malfunction

Solution: its reason normally is that connecting parts of the control panel and the internal circuits of the product may be loose or the control panel may be damaged. In this event, ask professional maintenance personnel to open the upper cover of the product and reconnect the connection parts of the control panel and internal circuit of the product, or replace the control panel.

9.4 Phenomenon of malfunction: during recording process of the ECG, there are disturbance of certain amplitude and order in the waveform, and there are obvious shakes of the baseline (namely the AC interference) as shown in the figure below:



Solution: it may be cause by the following reasons. Please check and eliminate the causes in sequence:

1）Whether the product is properly grounded?

2）Whether the connection of electrodes and leads are correct?

3）Whether conductive grease is smeared at the parts of skin that contact the electrodes?

4）Whether the metal patient bed is properly grounded?

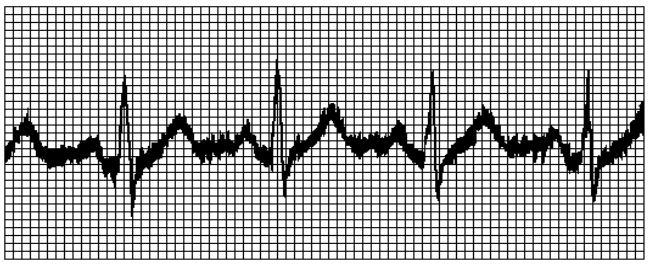
5）Whether the patient contacts the wall or the metal parts of the patient bed?

6）Whether there is any one who contacts the patient?

7）Whether there is any electrical equipment with high power working? (Such as X-ray set or ultrasonic products).

When the above causes are checked in sequence and no problem has been found and the disturbance cannot be eliminated still, please set the AC interference filter to current status in the product menu to effectively restrain the disturbance.

9.5 Phenomenon of malfunction: the baseline shakes abnormally on the ECG waveform (namely the muscle electricity disturbance) as shown in the figure below:



Solution: the cause to this phenomenon is mainly the over nervousness of the patient. Please check and eliminate the following causes in sequence:

1）Whether the environment and ambient temperature are convenient?

2）Whether the patient is overly nervous?

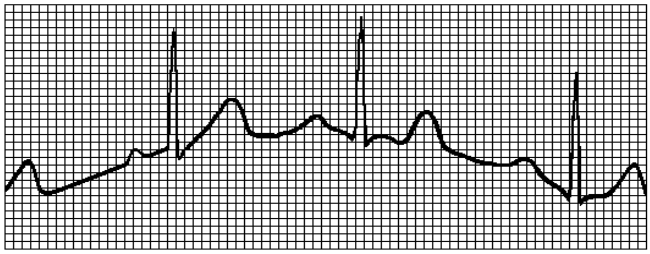
3）Whether the patient is overly nervous by the narrowness of bed?

4）Whether the patient spoke during recording process?

5）Whether the patient feels inconvenient by the tightness of the electrode clamps on the limbs?

When corresponding measures are taken to solve the above causes and the disturbance still exists, please set the muscle electricity disturbance filter to the current status on the product menu to effectively restrain the disturbance. However, after conducting the above measure, the ECG waveform recorded will be attenuated a little, especially for the R wave, so the doctor should pay attention to that.

## 9.6 Phenomenon of malfunction: the baseline of ECG waveform moves up or down irregularly (namely the baseline is unstable) as shown in the figure below.



Solution: The reason to this phenomenon is the instability of signals acquired. Please check and eliminate the following causes in sequence:

1）Whether the installation of electrodes is stable?

2）Whether the connection of the leads and electrodes are reliable?

3）Whether parts of the patient's skin that contact the electrodes are clean?

4）Whether limbs of the patient move or the breath of the patient is uneven during recording process?

5）Whether the old and new electrodes are use together during recording process?

When corresponding measures are taken to solve the above causes and the disturbance still exists, please set the baseline drift filter to the current status on the product menu to effectively restrain the disturbance

# Appendix A Technical Specification

## 1) Main unit

| | | |
|---|---|---|
| Lead | Standard 12-lead | |
| Acquisition mode | Simultaneous 12-lead acquisition | |
| Input mode | Floating input, have defibrillation protection effect and pacing pulse suppression | |
| Recording format | 1-channel | Automatic 1 channel, Automatic 2 channel, Manual 1 channel, Manual 2 channel |
| | 3-channel | Automatic 1 channel, Automatic 2 channel, Automatic 3 channel, Rhythm mode, Manual 1 channel, Manual 2 channel, Manual 3 channel, |
| Recording mode | Automatic | Record in appropriate format and automatic lead switch with measurement and analysis function |
| | Manual | Record in appropriate format and manual lead switch without measurement or analysis function. |
| Long term recording | Record for a long term (30-180 sec.) and rhythm analysis | |
| Measurement parameters: | Ventricular rate, PR interval, QRS time limit, QT/QTC interval,<br>P/QRS/T axis, RV5/SV1 amplitude and RV5+SV1 amplitude | |
| Input CIR current | ≤0.1μA | |
| Input impedance | >50MΩ | |
| Patient leak current | <10μA | |
| Time constant | ≥3.2s | |
| Frequency response | 0.05～150Hz | |
| Sensitivity threshold | ≤20μV（10Hz） | |
| Noise level | ≤15$\mu V_{p-p}$ | |
| Standard Sensitivity | 10mm/mV | |
| Scaling Voltage | 1mV | |
| Polarization resistance Voltage | ±500mV | |
| External input ( EXT) | Single-ended input | |
| | Input impedance | ≥100kΩ |
| | Sensitivity: | 10mm/V |
| External output (CRO) | Single-ended output | |
| | Output impedance | ≤100Ω |
| | Sensitivity | 1V/mV |
| Filter | AC: 50Hz, ≥20dB<br>EMG: 35Hz or 75Hz（-3dB） | |
| Sensitivity | 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20mm/mV | |
| Record speed | 6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s | |

## 2) Recorder

| | |
|---|---|
| Record mode | Hot array printing system |
| Resolution | ≥8dots/mm （Vertical）<br>≥16dots/mm（25mm/s）；≥8dots/mm（50mm/s）（Horizontal） |
| Paper speed | 6.25 mm/s，12.5 mm/s，25 mm/s，50mm/s |
| Recording Paper Specifications | Width of 63mm rolls |

## 3） LCD

| | |
|---|---|
| Display on LCD | The whole instrument work status, time, heart rate, and with the backlight |

## 4) others:

| | |
|---|---|
| Lead lines | Standard 12-lead wire protection without defibrillation |
| Safety Classification | IEC60601-1：2005 Class Ⅰ Type CF |
| power supply | AC：100 V -240V，50Hz，30VA |
| | DC：12V-1800mAh, Ni-MH battery |
| Fuse specification | 2-Φ5×20mm AC latency fuse<br>T800mA/250V |

# Appendix B Other Product specifications and environmental requirements

## B.1 Dimensions and weight

| | |
|---|---|
| Length × width × height | 360mm×325mm×86mm |
| Packing size | 400mm×300mm×200mm |
| Net weight | 3.0Kg |
| Gross weight | 4.3Kg |

## B.2 Environment requirements

| | | |
|---|---|---|
| 1 | Transportation | |
| | Environment temperature | -20℃～+55℃ |
| | Relative humidity | 25%～95% (No condensation) |
| | Air pressure | 70KPa～106KPa |
| | In accordance with the requirements stipulated in the contract order, the transport process to prevent rain and sun. | |
| | | |
| 2 | Storage | |
| | Environment temperature | -10℃～+40℃ |
| | Relative humidity: | 25%～80% |
| | Air pressure | 70KPa～106KPa |
| | The packaging of ECG stored in the non-corrosive gases and well-ventilated room. | |
| | | |
| 3 | Using | |
| | Environment temperature | +5℃～+40℃ |
| | Relative humidity: | 30%～80% |
| | Air pressure | 86KPa～106KPa |

# Appendix C Package and Accessories

## C.1 Accessories Along with the Machine

The standard configuration of the product normally contains the following accessories and documents in the following table with the quantities indicated below. When there are additional accessories contained in the user's order or contract, they will be listed in the product packing list, and the content of the table below will not be adjusted, so please check and accept the delivery according to the items in the product packing list.

| | |
|---|---|
| Instrument of ECG-101G | 1 unit |
| Patient Cable | 1 piece |
| Limb Electrode | 4 pieces |
| Chest Electrode | 6 pieces |
| Power Cable | 1 piece |
| Grounding Cable | 1 piece |
| Thermal Recording Paper | 1 piece |
| User's Manual | 1 copy |
| Qualified Certificate | 1 copy |
| Packing List | 1 copy |
| Certificate list | 1 copy |

## C.2 Matters Needing Attention

1) When opening the casing, check the integrity of packing case fist, and refuse to accept the product when the appearance of the packing case is damaged. When opening the packing case, please start with the top side of it;
2) After the case is opened, the user should check the accessories and documents according to the product packing list, and contact the business personnel of the company in case of unconformity;
3) Do not electrify the machine to conduct test run when the body case of the product is damage, and contact business personnel of the product immediately for treatment in that case;
4) Do not use accessories other than the originally provided accessories of the product, otherwise the performance and safety of the product may be affected;
5) The packing case must be properly kept for use in case of transportation for maintenan

# Appendix D Output Code and Interpretation of Analysis

## 8 Arrhythmia

| Code No. | Description |
|---|---|
| 8002 | Marked rhythm irregularity |
| 8110 | Sinus rhythm |
| 8102 | Sinus arrhythmia |
| 8108 | Marked sinus arrhythmia |
| 8120 | Sinus tachycardia |
| 8130 | Sinus bradycardia |
| 8200 | Atrial rhythm |
| 8210 | Atrial fibrillation |
| 82101 | Atrial fibrillation with rapid ventricular response |
| 82102 | Atrial fibrillation with slow ventricular response |
| 82103 | Atrial fibrillation with aberrant conduction, or ventricular premature complexes |
| 82108 | Atrial fibrillation with rapid ventricular response with aberrant conduction |
| 82109 | Atrial fibrillation with slow ventricular response with ventricular premature complexes |
| 8220 | Atrial tachycardia |
| 8250 | Atrial flutter |
| 82503 | Atrial flutter with aberrant conduction or ventricular premature complexes |
| 82505 | Cannot rule out atrial flutter |
| 8300 | Junctional rhythm |
| 8320 | Junctional tachycardia |
| 8400 | Supraventricualr rhythm |
| 8420 | Supraventricular tachycardia |
| 8430 | Supraventricular bradycardia |
| 8470 | with occasional supraventricular premature complexes |
| 8474 | with frequent supraventricular premature complexes |
| 8475 | with frequent supraventricular premature complexes in a pattern of bigeminy |
| 8500 | Ventricular rhythm |
| 8520 | Ventricular tachycardia |
| 8570 | with occasional ventricular premature complexes |
| 8574 | with frequent ventricular premature complexes |
| 8575 | with frequent ventricular premature complexes in a pattern of bigeminy |
| 86006 | Electronic atrial pacemaker |
| 86007 | Electronic ventricular pacemaker |
| 8901 | Undetermined regular rhythm |
| 8902 | Undetermined rhythm |
| 8970 | with occasional ectopic premature complexes |

| | |
|---|---|
| 8974 | with frequent ectopic premature complexes |
| 8975 | with frequent ectopic premature complexes in a pattern of bigeminy |

## 6 AV Conductive Defect

| Code No. | Description |
|---|---|
| 611 | Possible third degree AV block |
| 621 | Second degree AV block, Wenckebach type |
| 622 | Second degree AV block, Mobitz type II |
| 623 | First degree AV block |
| 631 | Short PR interval |
| 641 | Type-A WPW syndrome |
| 642 | Type-B WPW syndrome |
| 643 | Atypical WPW syndrome |
| 644 | Intermittent WPW syndrome |

## 7 Intraventricular Conductive Defect

| Code No. | Description |
|---|---|
| 711 | Left bundle branch block |
| 712 | Incomplete left bundle branch block |
| 721 | Right bundle branch block, plus possible RVH |
| 722 | Right bundle branch block |
| 723 | Incomplete right bundle branch block |
| 724 | RSR in lead V1/V2, consistent with right ventricular conduction delay |
| 731 | Left anterior fascicular block |
| 741 | Nonspecific intraventricular conduction block |

## 1 Myocardial Infarction

| Code No. | Description |
|---|---|
| 1113 | Cannot rule out anterior myocardial infarction, probably old |
| 1114 | Cannot rule out anterior myocardial infarction, age undetermined |
| 1121 | Possible anterior myocardial infarction, possible acute |
| 1122 | Possible anterior myocardial infarction, probably recent |
| 1123 | Possible anterior myocardial infarction, probably old |
| 1124 | Possible anterior myocardial infarction, age undetermined |
| 1131 | Anterior myocardial infarction, possible acute |
| 1132 | Anterior myocardial infarction, probably recent |
| 1133 | Anterior myocardial infarction, probably old |
| 1134 | Anterior myocardial infarction, age undetermined |
| 1213 | Cannot rule out anteroseptal myocardial infarction, probably old |
| 1214 | Cannot rule out anteroseptal myocardial infarction, age undetermined |
| 1221 | Possible anteroseptal myocardial infarction, possible acute |
| 1222 | Possible anteroseptal myocardial infarction, probably recent |
| 1223 | Possible anteroseptal myocardial infarction, probably old |
| 1224 | Possible anteroseptal myocardial infarction, age undetermined |
| 1231 | Anteroseptal myocardial infarction, possible acute |
| 1232 | Anteroseptal myocardial infarction, probably recent |
| 1233 | Anteroseptal myocardial infarction, probably old |
| 1234 | Anteroseptal myocardial infarction, age undetermined |
| 1313 | Cannot rule out anterolateral myocardial infarction, probably old |
| 1314 | Cannot rule out anterolateral myocardial infarction, age undetermined |
| 1321 | Possible anterolateral myocardial infarction, possible acute |
| 1322 | Possible anterolateral myocardial infarction, probably recent |
| 1323 | Possible anterolateral myocardial infarction, probably old |
| 1324 | Possible anterolateral myocardial infarction, age undetermined |
| 1331 | Anterolateral myocardial infarction, possible acute |
| 1332 | Anterolateral myocardial infarction, probably recent |
| 1333 | Anterolateral myocardial infarction, probably old |
| 1334 | Anterolateral myocardial infarction, age undetermined |
| 1413 | Cannot rule out septal myocardial infarction, probably old |
| 1414 | Cannot rule out septal myocardial infarction, age undetermined |
| 1421 | Possible septal myocardial infarction, possible acute |
| 1422 | Possible septal myocardial infarction, probably recent |
| 1423 | Possible septal myocardial infarction, probably old |
| 1424 | Possible septal myocardial infarction, age undetermined |
| 1431 | Septal myocardial infarction, possible acute |
| 1432 | Septal myocardial infarction, probably recent |
| 1433 | Septal myocardial infarction, probably old |

| | |
|---|---|
| 1434 | Septal myocardial infarction, age undetermined |
| 1513 | Cannot rule out lateral myocardial infarction, probably old |
| 1514 | Cannot rule out lateral myocardial infarction, age undetermined |
| 1521 | Possible lateral myocardial infarction, possible acute |
| 1522 | Possible lateral myocardial infarction, probably recent |
| 1523 | Possible lateral myocardial infarction, probably old |
| 1524 | Possible lateral myocardial infarction, age undetermined |
| 1531 | Lateral myocardial infarction, possible acute |
| 1532 | Lateral myocardial infarction, probably recent |
| 1533 | Lateral myocardial infarction, probably old |
| 1534 | Lateral myocardial infarction, age undetermined |
| 1613 | Cannot rule out inferior myocardial infarction, probably old |
| 1614 | Cannot rule out inferior myocardial infarction, age undetermined |
| 1621 | Possible inferior myocardial infarction, possible acute |
| 1622 | Possible inferior myocardial infarction, probably recent |
| 1623 | Possible inferior myocardial infarction, probably old |
| 1624 | Possible inferior myocardial infarction, age undetermined |
| 1631 | Inferior myocardial infarction, possible acute |
| 1632 | Inferior myocardial infarction, probably recent |
| 1633 | Inferior myocardial infarction, probably old |
| 1634 | Inferior myocardial infarction, age undetermined |
| 16132 | Cannot rule out inferior myocardial infarction with posterior extension, probably old |
| 16142 | Cannot rule out inferior myocardial infarction with posterior extension, age undetermined |
| 16212 | Possible inferior myocardial infarction with posterior extension, possible acute |
| 16222 | Possible inferior myocardial infarction with posterior extension, probably recent |
| 16232 | Possible inferior myocardial infarction with posterior extension, probably old |
| 16242 | Possible inferior myocardial infarction with posterior extension, age Undetermined |
| 16312 | Inferior myocardial infarction with posterior extension, possible acute |
| 16322 | Inferior myocardial infarction with posterior extension, probably recent |
| 16332 | Inferior myocardial infarction with posterior extension, probably old |
| 16342 | Inferior myocardial infarction with posterior extension, age undetermined |
| 171 | Abnormal Q wave ? [ Lat. ] |
| 172 | Abnormal Q wave ? [ Inf. ] |
| 173 | Abnormal Q wave ? [ Lat., Inf. ] |
| 174 | Abnormal Q wave ? [Ant. ] |
| 175 | Abnormal Q wave ? [ Ant., Lat. ] |
| 176 | Abnormal Q wave ? [ Ant., Inf. ] |
| 177 | Abnormal Q wave ? |

## 3 Ventricular Hypertrophy and Atrial Enlargement

| Code No. | Description |
|---|---|
| 311 | Possible right ventricular hypertrophy |
| 312 | Right ventricular hypertrophy |
| 313 | Right ventricular hypertrophy, probably repolarization abnormality |
| 321 | Minimal voltage criteria for LVH |
| 322 | Possible left ventricular hypertrophy |
| 323 | Moderate voltage criteria for LVH |
| 324 | Voltage criteria for LVH |
| 325 | Left ventricular hypertrophy, probably repolarization abnormality |
| 331 | Possible left atrial enlargement |
| 332 | Left atrial enlargement |
| 341 | Possible right atrial enlargement |
| 342 | Right atrial enlargement |

## 5 ST-T Abnormality

| Code No. | Description |
|---|---|
| 51 | ST abnormality, possible subendocardial ischemia |
| 52 | T wave abnormality, possible subendocardial ischemia |
| 53 | Nonspecific T wave abnormality |
| 54 | ST depression |
| 55 | Nonspecific ST elevation |
| 561 | Possible acute pericarditis |
| 562 | Acute pericarditis |
| 571 | ST elevation, possible acute myocardial infarction |
| 572 | Tall T wave, possible hyperkalemia |

## 2 Axis Deviation

| Code No. | Description |
|---|---|
| 21 | Moderate left axis deviation |
| 22 | Abnormal left axis deviation |
| 23 | S1-S2-S3 pattern |
| 24 | Abnormal right axis deviation |
| 25 | Right axis deviation |
| 26 | Indeterminate axis |

## 9 Others

| Code No. | Description |
|---|---|
| 911 | Low voltage |
| 912 | Low voltage in limb leads |
| 913 | Low voltage in chest leads |
| 941 | Long QT interval |
| 942 | Short QT interval |
| 971 | Dextrocardia ? |
| 972 | LIMB LEADS REVERSED |
| 973 | Abnormal QRS-T angle |
| 974 | Consistent with pulmonary disease |
| 981 | Artifacts present |
| 982 | Cannot be analyzed, re-record recommended |

## 10 Overall Judgment

| Code No. | Description |
|---|---|
| 1010 | Normal ECG |
| 1011 | Borderline ECG |
| 1012 | Atypical ECG |
| 1013 | Abnormal rhythm ECG |
| 1014 | Abnormal ECG |

**Note: The output codes may be subject to changes without notice.**